COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY

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DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled "**COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY**" submitted towards partial fulfillment of the requirements for the award of **MD in Anaesthesiology** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Sandeep Kundra**, Professor, Department of Anaesthesiology, **Dr. Richa Jain**, Assoc. Professor, Department of Anaesthesiology. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Family,

friends

&

Teachers

ACKNOWLEGEMENT

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Dr Jaspal Kaur

ABBREVIATIONS

µg	microgram/micrograms
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
cm of H_2O	centimeters of water
COPD	Chronic Obstructive Pulmonary Disease
ECG	Electrocardiogram
EMLA	Eutectic mixture of local anesthetics
ETT	Endotracheal tube
hr	hour
ID	Internal Diameter
Inj	Injection
INR	International normalized ratio
IV	Intravenous
kg	kilogram/kilograms
mg	Milligram/milligrams
$MgSO_4$	Magnesium sulphate
MPS	Mallampati Score
NIBP	Non-Invasive Blood Pressure
NMDA	N-methyl D aspartate
NRS	Numerical Rating Scale
NSAID	Non-steroidal anti-inflammatory drugs
PACU	Post Anesthesia Care Unit
POST	Postoperative sore throat
SD	Standard deviation
SpO_2	Peripheral oxygen saturation
VAS	Visual analogue scale

ABSTRACT

Introduction: Post operative sore throat (POST) is a common complication after endotracheal intubation often lasting for 12-24 hours after the surgery, with reported incidence of 30-65%. The potential causes of sore throat are believed to be irritation, mechanical trauma and inflammation due to the insertion of endotracheal tube (ETT) and cuff inflation. Various analgesics and anti-inflammatory drugs, have been utilized to lessen the frequency and intensity of postoperative sore throat (POST). Aspirin is a commonly used NSAID which acts by inhibiting the prostaglandin system. Aspirin gargles have been observed to significantly reduce the incidence and severity of POST. Magnesium sulphate, an NMDA receptor antagonist in a few preliminary studies has also seen to reduce POST. However, definitive evidence on the role of magnesium sulphate gargles for the prevention of POST is lacking.

Objective: To compare the efficacy and safety of preoperative gargles with aspirin and magnesium sulphate for prevention of postoperative sore throat.

Methods: A prospective, randomized, double blinded study was conducted on sixty adult patients of ASA grade I, II and III, between 18 to 65 years of age, of either sex posted for elective lumbar laminectomy surgery under general anaesthesia. Patients were randomly allocated into two groups of 30 patients each. In Group A, tab Aspirin 325mg and in Group B, 2 ml of Magnesium sulphate 50% w/v, were dissolved in 20 ml of 5% dextrose. Patients were instructed to gargle the study solution for 30 seconds, 15 minutes before induction of anesthesia. In PACU, incidence and severity of POST and NRS score were assessed at 1, 2, 4, 12 and 24 hours and post-operative cough was assessed at 0, 1, 2, 4, 12 and 24 hours.

Results: Incidence and severity of POST was significantly lower in magnesium sulphate group as compared to aspirin group at 1 hour postoperatively whereas it was found to be similar at 2, 4, 12 and 24 hours. NRS score for throat pain was significantly lower at 1, 2 and 4 hour in the magnesium group whereas it was comparable in both the groups at 12 and 24 hours. Incidence and severity of cough was similar at all the time intervals.

Conclusion: Hence, we conclude that magnesium sulphate gargles are more effective than aspirin in the early hours of postoperative period for reducing the incidence and severity of POST.

Keywords: Post-operative sore throat, Aspirin, Magnesium sulphate, Tracheal intubation, Cough

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KEY TO MASTERCHART

Category	Code	Inference
Sex	M	Male
	F	Female
POST		Post Operative Sore Throat
POST Grading	0	Grade 0
	1	Grade 1
	2	Grade 2
	3	Grade 3
Cough Grading	0	Grade 0
	1	Grade 1
	2	Grade 2
	3	Grade 3
Type of surgery	PIVD	Prolapsed intervertebral disc
American Society of Anaesthesiologists	ASA	Grade
	I	I
	II	II
	III	III
Numerical Rate Score	NRS	0-10
Cough (Y/N)	Y	Yes
	N	No
Adverse effects(Y/N)	Y	Yes
	N	No

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INTRODUCTION

Anesthesia in the present time is highly secure, remarkably adaptable and an indispensable component of patient care. Ensuring quality assurance is becoming increasingly crucial in enhancing postoperative results. Postoperative sore throat (POST) is a common complication after endotracheal intubation often lasting for 12-24 hours after the surgery, with reported incidence of 30-65%.[1-2] Most anesthesiologists regard POST as a minor and self-limiting problem. However, POST contributes to discomfort and morbidity for the patient.[3] It ranks as the 8th most frequently reported issue during the postoperative period.[3]

Multiple risk factors, such as age, female gender[4], head and neck surgery, the size[5] and cuff pressure[6] of endotracheal tube, difficult intubation, the duration of tracheal tube insertion, the number of suctioning attempts and postoperative nausea and vomiting have been documented as the potential causes of postoperative sore throat.[1] The manifestation of postoperative sore throat encompasses a variety of discernible signs and symptoms. Even if symptoms diminish without intervention, it is still advisable to manage postoperative sore throat as it contributes to enhancing patient satisfaction,[3,7,8] acceptance of anesthesia and improving post discharge activities.[8] Patients suffering from POST usually complain of irritation or itching in throat, discomfort, throat pain and coughing or hoarseness of voice. In addition, there can be difficulty in phonation which can be quite demoralizing for the patient. However, the exact cause and specific location of postoperative sore throat remains uncertain.

There are numerous factors that can contribute to POST and researchers have found that the incidence of POST can vary depending on the method of airway management.[1] For instance, endotracheal intubation is associated with a risk of trauma to the pharyngeal, laryngeal and tracheal structures. In contrast, the insertion of Laryngeal mask airway (LMA) is expected to result in localized mucosal injury in the supra glottic pharyngeal region, whereas the use of facemask with an oral airway is anticipated to cause injury limited to

the oropharyngeal region. Notably, the literature suggests that the incidence of POST following LMA insertion is, in some studies[9] comparable to that observed with endotracheal intubation, which is a more invasive procedure. Elevated endotracheal tube cuff pressure can lead to mechanical compression, causing mucosal hypo perfusion, ischemia, ulceration and pain and thereby, resulting in POST. Therefore, it is crucial to establish the cuff seal point following tracheal intubation and regularly monitor and adjust cuff pressure to ensure optimal settings. In a randomized control trial, conducted by Wang C et al in 2024, concluded that continuous monitoring and maintenance of tracheal tube cuff pressure were superior to merely monitoring without adjustment, effectively decreasing the incidence of POST within 24 h after extubation.[10]

POST has the potential to prolong hospital stay and lead to dissatisfaction[11] among the patients. Prevention of POST, therefore, is highly desirable.

In lumbar spine surgery, which is performed in the prone position, the incidence and severity of POST is expected to be higher and of greater severity due to the use of wire-reinforced tracheal tube which has a larger outer diameter[12] , requirement of concomitant use of a rigid stylet, and post intubation changes in patient position. Modifying the patient's position from a supine to prone orientation can result in alterations to endotracheal cuff pressure and displacement[13,14], which may subsequently influence the incidence of POST. Thus, efforts to reduce the occurrence of POST should be of high priority in this subset of patients.

Choi et al conducted a study on 98 patients, to compare the effects of dexmedetomidine and remifentanil on POST after spinal surgery in the prone position and came to the conclusion that dexmedetomidine infusion as an adjuvant significantly reduced the incidence and severity of POST in patients who underwent lumbar surgery 24 hours postoperatively.[15]

There have been several studies looking at potential interventions with some benefits to prevent POST. Though there have been many

suggestions to prevent POST but none of them have really gained much attention. Non pharmacological measures to prevent POST includes intubation using smaller size endotracheal tube,[16] lubrication of endotracheal tube with water soluble jelly, careful airway instrumentation, intubation after full relaxation, minimum cuff pressure, gentle suctioning of oropharynx and extubation with full deflation of tracheal tube cuff.[17]

When it comes to preventing POST, medication based treatment for pain and difficulty in swallowing is the best way. Intravenous (IV) dexamethasone due to its anti-inflammatory action has been widely used for prevention and management of POST.[18] However, hyperglycemia and predisposition to infection and poor wound healing due to use of steroids remain a concern.[19]To overcome this, various other pharmacological interventions have been employed which include aspirin gargles, inhalation of beclomethasone[20] or gargling with azulene [21] or spraying benzydamine[22] on endotracheal tube cuff, use of topical or systemic lidocaine,[23] ketamine gargles[24], zinc lozenges,[25] amyl m cresol , ketoprofen, licorice[26] and magnesium sulphate gargles.[27]

Aspirin is a commonly used, over the counter available Non Steroidal Anti Inflammatory Drug (NSAID) having analgesic, anti-pyretic and local anesthetic properties. Its action is mediated by inhibiting the prostaglandin system. Aspirin gargles have been observed to significantly reduce the incidences and severity of POST. [28]

Magnesium, N-methyl D aspartate (NMDA) receptor antagonist[29,30] acts as anti inflammatory and anti nociceptive by inhibiting NMDA Ca2+ influx. NMDA receptors also exist peripherally[31] and inflammation stimulate peripheral NMDA receptors. Intravenous administration of magnesium has been demonstrated to have efficacy similar to that of dexamethasone for prevention of POST.[32] Gupta et al conducted a study on the effectiveness of preoperative nebulization of magnesium sulphate and that it significantly reduced the incidence and severity of POST during rest and swallowing at all time points.[33] Borazan et al found magnesium lozenges to be effective for the

prophylaxis of POST and attributed this effect to its wound healing properties.[34] Following this, Chattopadhay et al compared magnesium sulphate (MgSO4) gargles with aspirin gargles for the prevention of POST and found these to be superior.[27] This is the only study in which MgSO4 gargles have been compared with aspirin gargles for the prevention of POST. The study, however was performed in patients undergoing short duration, ambulatory surgery.[27] This cohort of patients have a less incidence of POST as compared to patients undergoing spine surgery in prone position.

Thus, the present study was planned to compare the efficacy of pre-induction gargles with magnesium sulphate and aspirin for prevention of POST in patients undergoing lumbar laminectomy in prone position.

AIMS AND OBJECTIVES

To compare the efficacy and safety of preoperative gargles with aspirin and magnesium sulphate for prevention of postoperative sore throat.

REVIEW OF LITERATURE

Postoperative sore throat (POST) after endotracheal intubation is a common and annoying complication to the patient. Postoperative sore throat is a result of local tissue trauma due to laryngoscopy and endotracheal intubation, leading to the inflammation of pharyngeal mucosa. Tracheal intubation is associated with higher risk of postoperative sore throat than with a supraglottic airway or facemask.[1,35,36] It causes trauma of the larynx posteriorly over the cricoid plate, along the vocal processes of arytenoids and along the anterior tracheal wall.

POST is attributed to multiple perioperative conditions, including local irritation and inflammation of airway, [37] large size of the tracheal tube, increased duration of surgery, movement of tracheal tube and cuff during position change, airway damage after intubation using rigid stylet and prone position[38]. Airway trauma during intubation or multiple attempts at intubation results in congestion and edema of pharyngo-laryngeal mucosa, increasing the incidence and severity of POST.

Increased cuff pressure can also contributes to postoperative sore throat [39]. Unrestricted cuff pressure has the potential to cause harm to the tracheal mucosa through direct trauma and reduced blood flow.[40]

To reduce this complication, most measures have been directed at limiting the physical trauma from airway instrumentation and limiting the endotracheal tube cuff pressure. Although cuff pressure manometers are currently accessible for evaluating cuff pressure adequacy, their utilization remains limited as clinicians continue to rely on subjective techniques such as pilot ballon palpation or detecting audible air leak.[41] In the year 2016, Sangeetha and Jacob et al registered 150 patients who were intubated by anesthesiologists with at least five years of experience. If the cuff pressure exceeded 30cm of H_2O, it was deemed high, and if it was below 20 cm of H_2O, it was considered low. Anesthesiologists were able to inflate the cuff to an optimal cuff pressure in 64% of the cases. In 17.3% of the cases, the cuff pressures were recorded as low, while in 18.7% of the cases the

cuff pressure reached above the optimal range. They observed that even the experienced anesthesiologists cannot achieve the optimal endotracheal tube cuff inflation pressure solely through subjective assessment.[42] Several non-pharmacological and pharmacological interventions have been evaluated for the prevention of POST, such as use of smaller endotracheal tube, topical or intravenous corticosteroids or local anesthetics, ketamine gargles, topical application of magnesium and others [38].

In 2006 Aggarwal et al conducted a prospective, randomized single blind study for evaluation of aspirin and benzydamine hydrochloride for attenuating postoperative sore throat prevention on 60 patients, concluded that Aspirin and benzydamine hydrochloride gargles significantly reduced the incidence and severity of postoperative sore throat (POST) [28].

Salama and Badawy in a study reported that preoperative nebulization with dexamethasone 8mg reduces the incidence and severity of postoperative sore throat in patients receiving general anesthesia with endotracheal intubation [43].

Gupta D and Ghanshyam Y studied the efficacy of licorice gargles for attenuating postoperative sore throat on 40 adults of 18-60 years of age, ASA I and II of either sex, undergoing elective lumbar laminectomy concluded that POST and post extubation cough was reduced in licorice group compared with control group. There was no side effects between groups[44].

In an another study ,Ogata et al. observed that preoperative gargling with azulene reduced the incidence of POST from 65% to 25% in patients due to its anti- inflammatory effects[21].

A study conducted on comparison between betamethasone gel and lidocaine jelly applied over the tracheal tube to reduce postoperative sore throat, cough and hoarseness of voice. One hundred and fifty ASA physical status I and II patients undergoing elective surgeries in general orotracheal anesthesia were randomized into three groups: betamethasone gel, lidocaine jelly, and control groups. They evaluated that the incidence of postoperative sore throat, cough, and hoarseness

of voice was significantly lower in the betamethasone group compared with the other two groups and came to the conclusion that wide spread application of betamethasone gel on the tracheal tube decreases the incidence and severity of postoperative sore throat, cough, and hoarseness of voice.[45]

Canbay et al conducted a study on ketamine gargles for attenuating postoperative sore throat after endotracheal intubation on Fourty six, ASA I and II patients and concluded that POST was significantly less in patients administered with ketamine gargles at 0, 2 and 24hours.[24]

Borazan et al in 2012 conducted a study on magnesium lozenges and placebo group and concluded that the severity of POST was significantly lower in magnesium group at 0 and 2 hour. The incidence of POST however was similar in both groups at 24 hours.[34]

Farhang B and Grondin L in 2017 conducted a study on the effect of Zinc lozenges on postoperative sore throat prevention and concluded that the severity of POST was significantly lower in the zinc group for mild and moderate POST.[25]

Subedi et al in 2019 conducted a prospective, randomized, double blind study on the effect of intravenous lidocaine(L), dexamethasone(D) and their combination (DL) on postoperative sore throat and concluded that the incidence of a sore throat was 36%, 43%, 25% and 56% in Group D , L , DL and NS. Dexamethasone with or without lidocaine reduced the incidence of the postoperative sore throat (POST). No differences was observed in the severity of sore throat, cough and hoarseness among the groups.[46]

Kumar et al conducted a study in 2017 on postoperative sore throat in head and neck surgeries under endotracheal intubation and laryngeal mask anesthesia. During different cuff pressure and size of tube or mask, pain score was measured. They concluded that the postoperative sore throat can be effectively reduced by LMA but they were not able to find any correlation of pain score with different cuff pressure and size of tube or mask[47].

Dipanjan et al conducted a study on the efficacy of intravenous dexamethasone to reduce the incidence of postoperative sore throat and concluded that in the first 24hrs there is overall decrease in the incidence and the severity was lower after prophylactic intravenous dexamethasone. Postoperative sore throat is caused by aseptic inflammatory process to the tracheal mucosa during laryngoscopy, increased cuff pressure and during extubation. Dexamethasone prevents POST by inhibiting metabolism of arachidonic acid, thus reducing cytokine release[48].

In the year 2015, Teymourian et al conducted a study to compare the efficacy of magnesium sulphate and ketamine gargles on incidence and severity of POST and came to the conclusion that the number of patients with sore throat were significantly lower in magnesium group compared to ketamine at 2 and 24 hours and Visual Analogue Scale (VAS) score was significantly lower in magnesium group at 2 and 24 hours after the surgery.[49]

Park et al proposed a randomized study in 2015 and concluded that the prophylactic magnesium sulphate appears to be non-inferior to dexamethasone for prevention of POST at rest in patients undergoing lumbar spinal surgery in the prone position.[32]

In the year 2023, Murugaiyan, et al observed that topical application of EMLA cream on the endotracheal tube cuff significantly reduced the incidence and severity of POST, cough, and postoperative hoarseness of voice in the first six hours of surgery compared to the lubricant gel group.[50]

In another prospective randomized study conducted by Sheikh, et al in 2019 for evaluation of efficacy of intravenous magnesium sulphate versus dexamethasone for prevention of postoperative sore throat in patients undergoing lumbar spine surgery in prone position.[51] They noted that both incidence and severity of sore throat and incidence of hoarseness was more in placebo group than magnesium sulphate group and dexamethasone group and was comparable between magnesium sulphate and dexamethasone groups.

In 2017, Rajan S et al recognized in a prospective, randomized study that ketamine and magnesium sulfate nebulization, 15 minutes before induction of general anesthesia and intubation, significantly decrease POST at 0, 2, and 4 hour, and postoperative hoarseness at 0 hour. This study also revealed the decrease in the incidence and severity of sore throat, hoarseness, and cough at all periods in the study groups as compared with control.[52]

A randomized study conducted in 2013 at Aga Khan University Hospital, Nairobi, to evaluate the effects of intravenous diclofenac sodium on postoperative sore throat in patients undergoing laparoscopic surgery and analysed that there was no statistically significant difference in the occurrence or severity of postoperative sore throat between the diclofenac and standard treatment groups at 2, 6 and 18 hours postoperatively. In addition at 2 and 6 hours postoperatively, fewer patients in the diclofenac group had POST compared to the standard treatment group even if this difference was not statistically significant and by 18hrs the occurrence of POST was equal in both groups.[53]

In another study, Ahuja V et al analysed that the use of pre-operative ketamine nebulisation reduced the incidence and severity of POST during early post-operative period in patients receiving GA with tracheal intubation.[54]

Yadav and colleagues carried a study to compare the efficiency of preoperative nebulization in reducing the incidence of POST following GA. among 100 cases divided into two equal groups.[55] Group A nebulized with 3 ml of normal saline and Group B nebulized with 3 ml of 225 mg isotonic nebulized magnesium sulfate for 15 minutes, 5 minutes before induction of anesthesia. They found no significant difference in POST at rest during 0^{th}, 2^{nd} and 4^{th} hour between normal saline and $MgSO_4$. Meanwhile, significant difference was seen at 24^{th} hour, where $MgSO_4$ lessens POST. Magnesium sulphate significantly reduces the incidence of POST compared to normal saline.

Bhanwra et al, in the year 2024, conducted a randomized control trial on the role of preoperative zinc, magnesium and budesonide gargles[56] in postoperative sore throat. Patients were randomised into three groups; group Z received 40 mg Zinc, group M received 250 mg Magnesium Sulphate and group B received 200 µg Budesonide in the form of 30 ml tasteless and colourless gargle solutions. Sore throat assessment and hemodynamic recording was done postoperatively at immediate recovery (0 h) and 2, 4, 6, 8, 12 and 24 h post-operatively. They observed that Magnesium, zinc and budesonide have an equivocal effect in the prevention of POST at different time points. The incidence of sore throat increases significantly in surgeries lasting more than two hours if magnesium or budesonide have been used as premedicant. Duration of surgery is an independent predictor for POST.

Aspirin has been used in many studies for the prevention of POST but there has been only one study comparing aspirin with magnesium for the prophylaxis of POST.[27] Thus, there is dearth of literature on the relative efficacy of aspirin and magnesium for prophylaxis of POST. Therefore, the present study has been designed to evaluate the efficacy of Aspirin and Magnesium sulphate gargles for prevention of postoperative sore throat in patients undergoing lumbar laminectomy in prone position.

MATERIAL AND METHODS

SOURCE OF DATA

The study was conducted in a prospective, randomized, double blinded manner in the department of Anaesthesiology, DMCH, Ludhiana after obtaining clearance from hospital ethics committee. Sixty patients of either sex between age group 18 to 65 years belonging to ASA grade I,II and III scheduled for elective lumbar laminectomy under general anaesthesia were randomly allocated to two groups of 30 patients each.

Group Allocation

Patients were randomly allocated into two groups, Group A and B, of 30 patients each using computer generated random number list which were kept in a sealed opaque envelope and opened by an anaesthesia resident. The study solution was prepared and administered by an anesthesia resident who did not participate in the data collection. Patients in both groups were instructed to gargle the study solution for 30 seconds, 15 minutes before induction of anesthesia.

In Group A – The patients were given a gargle solution prepared by dissolving a tablet of Aspirin 325 mg in 20 ml of 5 % dextrose.

In Group B – The patients were given a gargle solution prepared by dissolving 2 ml of Magnesium sulphate (50 % w/v) in 20 ml of 5 % dextrose.

METHOD OF COLLECTION OF DATA

INCLUSION CRITERIA:

- Adult patients of age 18-65 years of either sex posted for elective lumbar laminectomy under general anaesthesia with endotracheal intubation.
- American Society of Anesthesiologists (ASA) Status I, II and III.

EXCLUSION CRITERIA:

- Patient refusal.
- Any known hypersenstivity or contraindication to aspirin, magnesium sulphate.
- Recent H/O Sore throat.

- Pregnant & lactating mothers.
- Anticipated difficult intubation, MPS Grade III and IV.
- Patients receiving chronic treatment with calcium channel blocking drugs or magnesium.
- Patients on steroids.
- History of reactive airway disease like bronchial asthma or COPD.

ANAESTHESIA TECHNIQUE

A detailed pre-anaesthetic checkup was conducted preoperatively one day prior to surgery comprising of detailed history, general physical and systemic examination. Routine investigations like complete hemogram, prothrombin time/INR, urine routine, renal function tests, random blood sugar, chest X-ray and ECG were obtained. Patients were counselled and explained about the scoring system to be used for evaluation of POST.

All patients were kept nil per oral before surgery. This fasting period was eight hours for solids and 4 hours for clear liquids. Pre-medication in the form of tab alprazolam 0.5 mg on the night before surgery was administered to all patients. Vitals were monitored again in the pre-operative holding area. Fifteen minutes before induction of anaesthesia, patients were requested to perform gargles for 30 seconds using the study drug solution as per group allocated. Patient was kept unaware of the nature of the drug administered.

Throat examination was done by the anaesthesia resident pre and post gargles and after extubation.[57]

After arrival of patient to the operating room, standard monitoring including continuous electrocardiography (ECG), non-invasive blood pressure (NIBP) and oxygen saturation by pulse oximeter (SpO_2) were started and baseline parameters were recorded. Intravenous line was secured using an 18 gauge cannula and intravenous fluid was infused.

After standard anaesthesia induction, using intravenous propofol, patients were paralyzed using Inj atracurium 0.5 mg/Kg and endotracheal intubation was performed using a high volume, low

pressure cuffed flexometallic endotracheal tube (Romsons) of size 7.5 mm internal diameter (ID) for females and 8.0 mm ID for males. The ETT with stylet but without lubrication was inserted using direct laryngoscopy technique by a designated anesthesia consultant. Any patient who required more than one attempt of intubation was excluded from the study. Endotracheal tube cuff was inflated. After ensuring correct placement of ETT, all patients were mechanically ventilated. Anaesthesia was maintained using oxygen, nitrous oxide and desflurane. ETT cuff pressure was measured every 30 minutes using ETT cuff pressure manometer and maintained between 22-25 cmH2O by deflating the pilot cuff, a little, if so required. Intra-operative analgesia was provided by bolus injections of fentanyl. Volatile agent concentration, muscle relaxant and analgesic administration were titrated as per the discretion of anaesthesiologist. At the end of surgery, patients were administered Inj ondansetron 0.1mg/kg and paracetamol 15mg/kg intravenous infusion. After completion of surgery, neuromuscular blockade was reversed using Inj neostigmine 0.05mg/kg and glycopyrolate0.01mg/kg. On return of patient's consciousness and spontaneous respiratory efforts, ETT was removed after gentle suctioning of the oropharynx and deflating the ETT cuff. After extubation, patients were shifted to Post anaesthesia care unit (PACU) for observation.

Upon arrival of patient in the PACU, patients underwent evaluation by an anaesthesia resident blinded to the study. The resident assessed the patient's severity of POST by a 4 point scale,[28] pain intensity was measured with NRS score at 1, 2, 4, 12 and 24 hours and post-operative cough was assessed at 0, 1, 2, 4, 12 and 24 hours by grading of cough.[58]

Severity grading scale of POST, wherein

GRADE 0- No sore throat

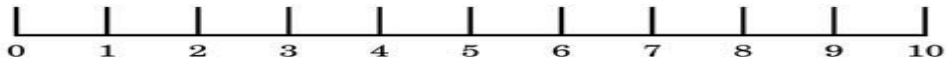
GRADE 1-Mild sore throat (complains only on asking)

GRADE 2-Moderate sore throat (complains on his /her own)

GRADE 3-Severe sore throat (hoarseness, throat pain)

Intensity of pain was measured with Numerical Rating Scale (NRS), marked from 0 to 10, where 0 means no sore throat and 10 means worst imaginable pain in throat.

NUMERICAL RATING SCALE



No Pain

Worst Pain

Severity grading scale of cough, wherein

GRADE 0- No cough

GRADE 1-Mild cough (less than common cold)

GRADE 2-Moderate cough (similar to common cold)

GRADE 3-Severe cough (more than common cold)

Patients were asked whether they experience any side effects related to the gargle solution.

OUTCOME:

PRIMARY OUTCOME:

1. Incidence of sore throat at 1, 2, 4, 12 and 24 hours.

2. Severity of sore throat as assesed by subjective grading score and NRS.

SECONDARY OUTCOME:

1. Incidence and severity of post extubation cough at 0, 1, 2, 4, 12 and 24 hours.

STATISTICAL ANALYSIS:

Data were described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data is normally distributed, a Kolmogorov-Smirnov test was used.

Comparison of quantitative variables between the study groups were done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively.

For comparing categorical data, Chi square ($\chi 2$) test and fisher exact test was used when the expected frequency was less than 5. A probability value (p value) less than 0.05 was considered statistically significant.

All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

SAMPLE SIZE CALCULATION

By using previous study[27], the Postoperative sore throat is 18% in magnesium group and 39% in Aspirin group.

Based on this assumption

The formula used in the situation is as under:

$$n = \frac{[Z_{1-\alpha/2}\sqrt{2\,P\,(1-P)} + Z_{1-\beta}.\sqrt{\{P1(1-P1) + P2\,(1-P2)\}}]^2}{(P1-P2)^2}$$

Where P=(P1+P2)/2

- Approximate value of efficacy/cure rate for standard treatment =P1
- Approximate value of efficacy/cure rate for other treatment = P2
- Effect size = (P2-P1)
- Level of significance (usually 5%)
- Zα = Value of standard normal variate corresponding to α level of significance (1.96)
- Zβ = The standard normal deviate for desired power (0.842)

With the above assumptions the sample size for 95% confidence level & 80% power works out 66 in each group.

OBSERVATIONS AND RESULTS

This prospective, randomized and double blinded study was conducted in Department of anesthesiology, DMCH Ludhiana on a total of 60 adult patients from October 2022 to November 2023. Patients were randomly allocated into two groups- Group A (Aspirin) and Group B (Magnesium sulphate)

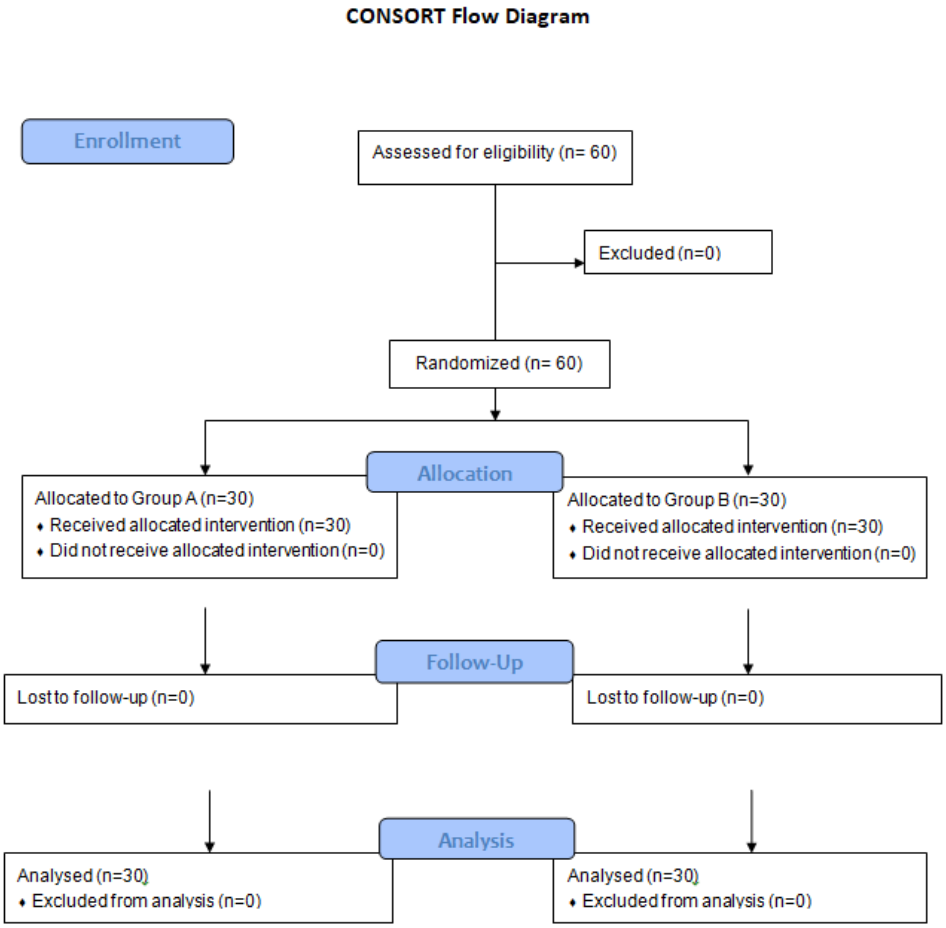


FIGURE1: CONSORT FLOW DIAGRAM OF THE STUDY.

A total of 60 patients were enrolled for the study and no patient was excluded from the study. 60 patients were randomly allocated by computer generated random number, in two group. All patients were assessed in PACU. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

A. DEMOGRAPHIC PROFILE

Table 1: Mean age distribution

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
Age(years)	50.63	11.85	47.57	11.92	0.176

Mean age of patients in group A was 50.63 ± 11.83 years whereas it was 47.57 ± 11.92 years in group B. There was no significant difference between both the groups with respect to age, p value being 0.176 [Table 1, Figure 2].

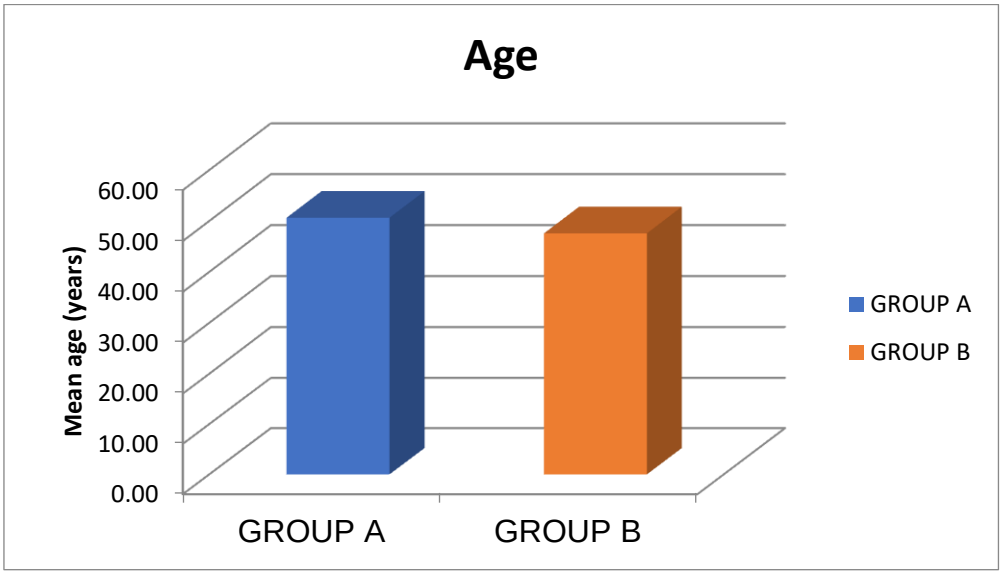


Figure 2: Mean age distribution

Table2: Sex distribution

		GROUP				Total	p-value
		A	A	B	B		
Sex	Female	14	46.7%	11	36.7%	25	0.432
	Male	16	53.3%	19	63.3%	35	
Total		30	100.0%	30	100.0%	60	

In group A, 46.7% and 53.3% of the patients were female and male respectively. In group B, 36.7% of the patients were female and 63.3% were male. Both the groups had a similar distribution of male and female patients with no statistically significant difference between them. p-value was measured to be 0.432 as shown in Table 2, Figure 3.

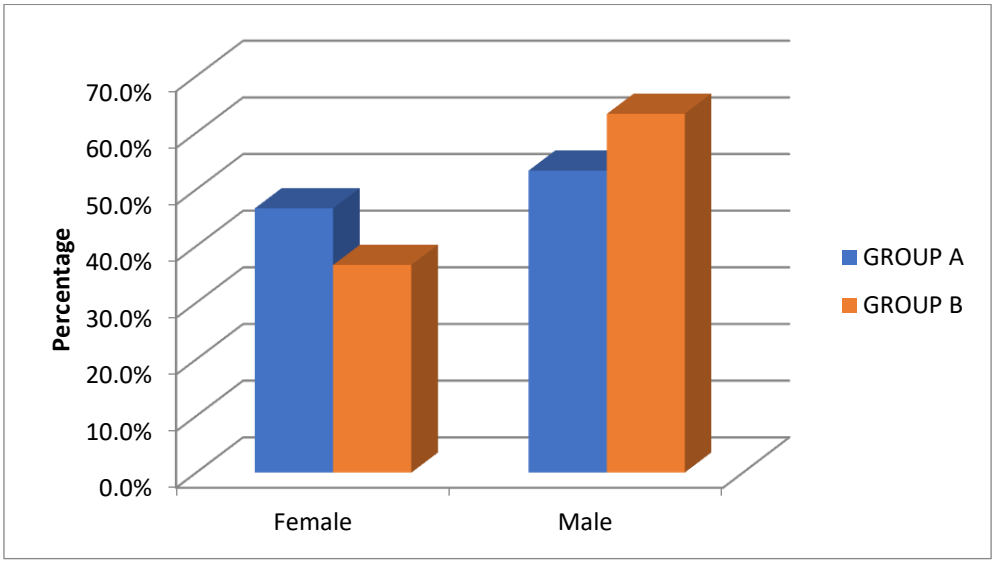


Figure 3: Sex distribution

Table 3: Mean Height Distribution

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
Height(cm)	170.47	7.14	170.47	7.20	0.840

Mean height of the patients in group A was 170.47 ± 7.14 cm and in group B was 170.47 ± 7.2 cm. The difference in mean height did not show statistical significance (p-value of 0.840, depicted in Table 3, Figure 4).

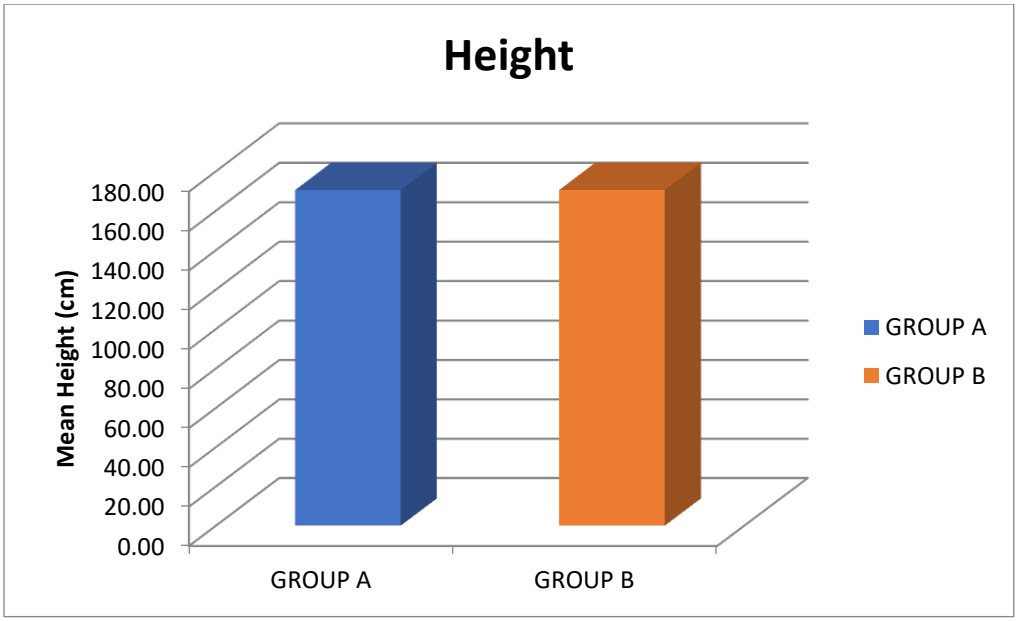


Figure 4: Mean Height Distribution

Table 4: Mean Weight Distribution

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
Weight	76.83	15.09	75.67	10.14	0.678

Mean weight of patients in group A was 76.83 ± 15.09 kg compared to 75.67 ± 10.14 kg in group B. However the difference in mean weight between the two groups was statistically insignificant with p-value 0.678. [Table 4, Figure 5]

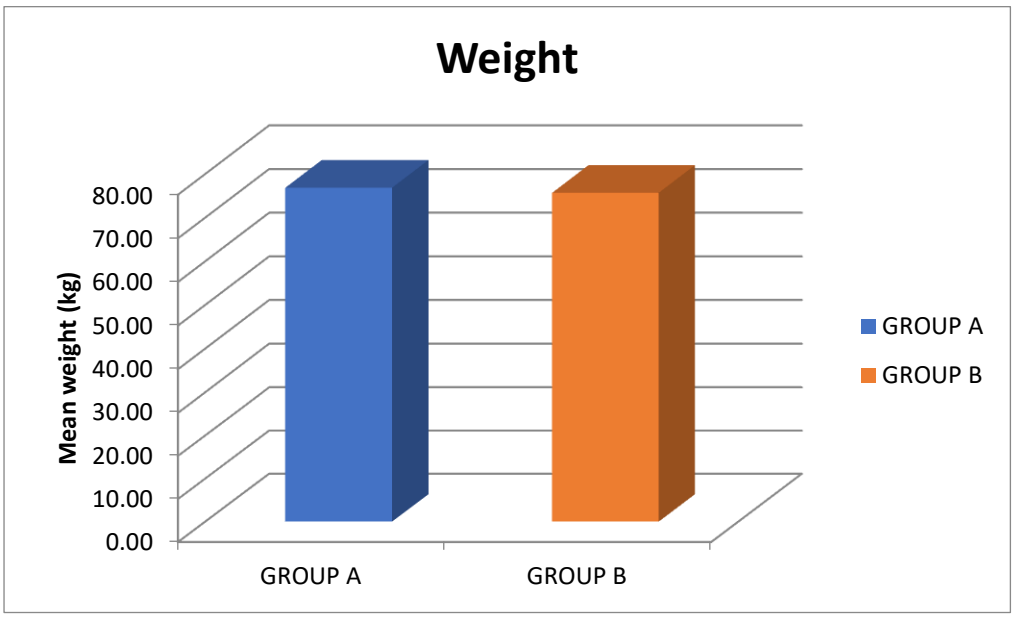


Figure 5: Mean weight distribution

Table 5: Mean BMI distribution

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
BMI	26.27	3.47	26.03	3.23	0.762

Mean BMI values calculated for the two groups, 26.27 ± 3.47 kg/m^2 in group A and 26.03 ± 3.23 kg/m^2 in group B, didn't exhibit a statistically significant difference as indicated by a p- value of 0.762 [Table 5, Figure 6]

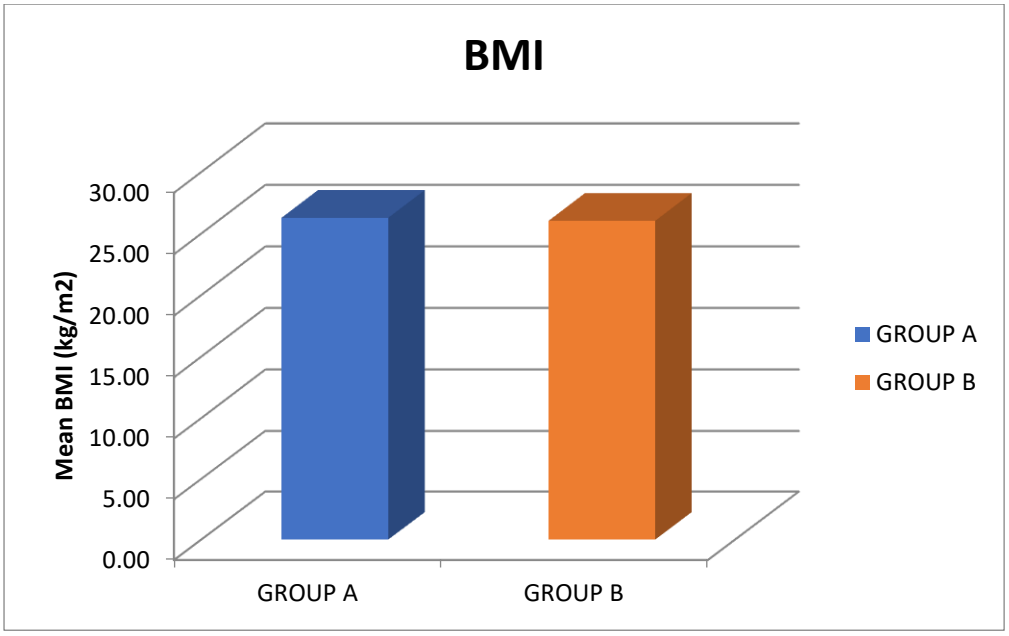


Figure 6: Mean BMI distribution

Table 6: ASA physical status

		GROUP A		GROUP B		Total	p-value
		No. of cases	%age	No. of cases	%age		
ASA Grade	I	2	6.7%	3	10.0%	5	0.871
	II	21	70.0%	21	70.0%	42	
	III	7	23.3%	6	20.0%	13	
Total		30	100.0%	30	100.0%	60	

Patients belonging to ASA I to III were enrolled in the study. The ASA class distribution in both the groups were similar, the difference being statistically non-significant with p-value= 0.871. [Table 6, Figure 7]

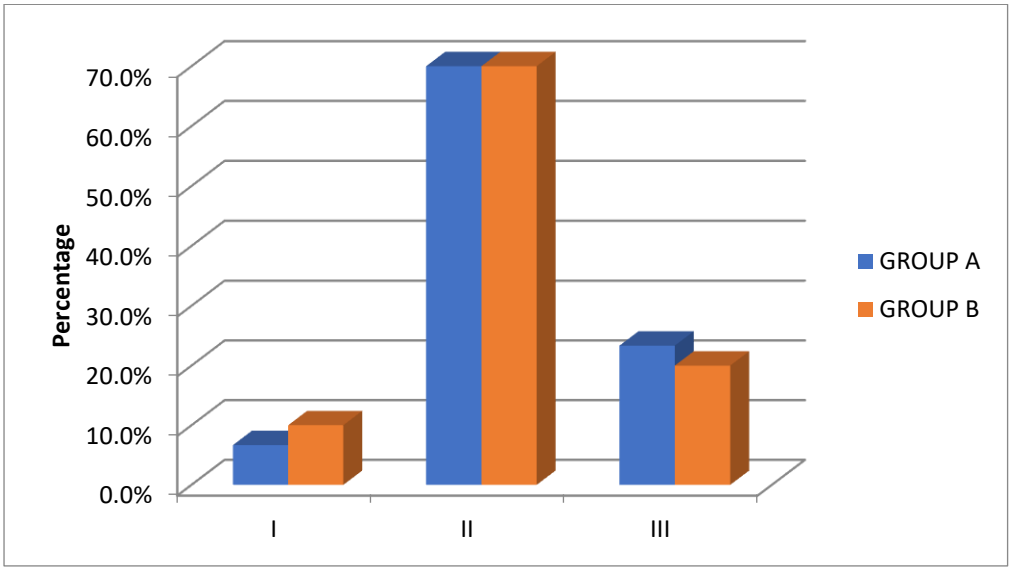


Figure 7: ASA physical status

Table 7: Mean duration of anaesthesia

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
Duration of anaesthesia (in minutes)	209.83	40.18	204.50	30.41	0.893

The mean duration of anaesthesia in group A was 209.83±40.18 minutes whereas group B exhibited a mean duration of 204.50±30.41 minutes. Notably, the difference between the two groups were statistically non-significant with a p value 0.893 as presented in Table7, Figure 8

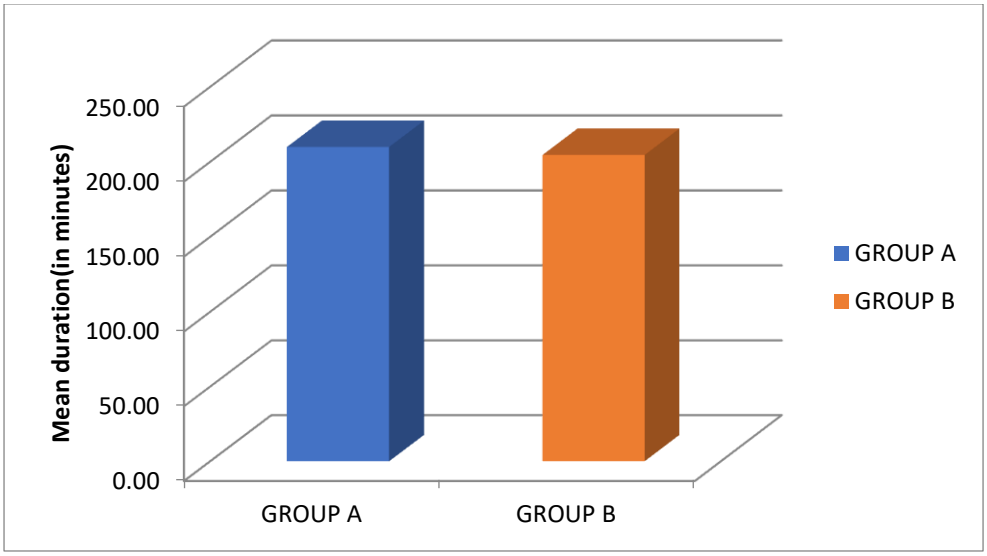


Figure 8: Mean duration of anaesthesia (in minutes)

Table 8: MEAN ENDOTRACHEAL CUFF PRESSURE

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
At 30min	23.20	1.00	23.47	0.90	0.281
At 60min	23.53	0.86	23.13	1.01	0.104
At 90min	23.53	0.86	23.53	0.86	1.000
At 120min	23.40	0.93	23.60	0.81	0.380
At 150min	23.67	0.76	23.93	0.37	0.088
At 180min	23.75	0.68	23.84	0.55	0.612

The endotracheal cuff pressures were monitored intra-operatively, after every 30 minutes and was maintained between 22-25 cm of H_2O when found to be increased. In the two groups, No significant difference was noted in endotracheal cuff pressure measured intra-operatively with p-value 0.893 as presented in Table 8.

B. INCIDENCE OF POSTOPERATIVE SORE THROAT(POST)

The assessment for POST was conducted at 1, 2, 4, 12 and 24 hours in PACU.

Table 9: Incidence of postoperative sore throat (POST) at 1, 2, 4, 12 and 24 hours

	GROUP A	GROUP B	Total	p-value
Incidence of POST	n=30	n=30		
1 hour	30 (100.0%)	24 (80.0%)	54	0.010
2 hour	21 (70.0%)	17 (56.7%)	38	0.288
4 hour	3 (10.0%)	4 (13.3%)	7	0.69
12 hour	2 (6.7%)	4 (13.3%)	6	0.393
24hour	0 (0.0%)	0 (0.0%)	0	

The Incidence of POST at 1 hour was 100% in group A whereas it was 80% in group B. Thus, the incidence of postoperative sore throat at 1 hour was lower in group B than group A. The difference was statistically significant with p value 0.010 as shown in Table 9. Post-operatively, at 2, 4, and 12 hour interval the incidence of POST was similar among the two groups with p-values, 0.288, 0.69 and 0.393 respectively. At 24 hours postoperatively, none of the patient experienced POST.

C. SEVERITY OF POSTOPERATIVE SORE THROAT(POST)

Table 10 : Severity of postoperative sore throat (POST) at 1 hour

		GROUP				Total	p-value
		A		B			
Grading of POST	0	0	0.0%	6	20.0%	6	0.002
	1	24	80.0%	24	80.0%	48	
	2	6	20.0%	0	0.0%	6	
	3	0	0.0%	0	0.0%	0	

Grade 0 POST was reported by none of the patients in group A, while 20% of the patients in group B had grade 0 POST. The incidence of grade 1 POST was similar at 80% in both the groups. 20% of the patients in group A developed grade 2 POST while no patients in group B experienced grade 2 POST. None of the patients in either group reported POST severity score of 3. Thus, the severity of postoperative sore throat at 1 hour was lower in group B than group A. The difference was statistically significant with p value 0.002 as shown in Table 10.

Table 11: Severity of postoperative sore throat (POST) at 2 hour

		GROUP				Total	p-value
		A		B			
Grading of POST	0	9	30.0%	13	43.3%	22	0.242
	1	19	63.3%	17	56.7%	36	
	2	2	6.7%	0	0.0%	2	
	3	0	0.0%	0	0.0%	0	

At 2 hour postoperatively, the incidence of grade 0 POST in group A was 30% whereas it was 43.3% in group B. 63.3% of the patients in group A and 56.7% of the patients in group B developed grade 1 POST. Grade 2 POST occurred in 6.7% of the patients in group A, whereas no patients (0%) in group B developed grade 2 POST. Neither group A nor group B had any patients who experienced grade 3 POST. Overall, The severity of POST at 2 hour was similar among both the groups with a p-value of 0.242 as shown in Table 11.

Table 12: Severity of postoperative sore throat (POST) at 4 hour

		GROUP				Total	p-value
		A		B			
Grading of POST	0	27	90.0%	26	86.7%	53	0.601
	1	3	10.0%	3	10.0%	6	
	2	0	0.0%	1	3.3%	1	
	3	0	0.0%	0	0.0%	0	

At 4 hours postoperatively, grade 0 POST was seen in 90% of the patients in group A, whereas it was 86.7% in group B. The incidence of grade 1 POST was similar at 10% in both the groups. 3.3% of the patients in group B reported grade 2 POST, compared to none in group A. Grade 3 POST was not reported in any of the patients, in either of group A or B. Thus, the severity of postoperative sore throat were higher in group B compared to group A at 4 hour postoperatively but the difference did not achieve statistical significance with a p value of 0.601 as shown in Table 12.

Table 13: Severity of postoperative sore throat (POST) at 12 hour

		GROUP				Total	p-value
		A		B			
Grading of POST	0	28	93.3%	26	86.7%	54	0.108
	1	2	6.7%	0	0.0%	2	
	2	0	0.0%	3	10.0%	3	
	3	0	0.0%	1	3.3%	1	
Total		30	100.0%	30	100.0%	60	

93.3% of the patients in group A had grade 0 POST, compared to 86.7% in group B. Grade 1 POST was seen in 6.7% of the patients in group A, and in group B, no patient was reported to had grade 1. None of the patient in group A experienced grade 2 POST while it was seen in 10% of the patients in group B. There were no cases of grade 3 POST in group A, whereas group B had a 3.3% incidence of grade 3 POST. Therefore, the severity of POST at 12 hour postoperatively was similar among the two groups (p-value = 0.108, Table 13)

Table 14: Severity of postoperative sore throat (POST) at 24 hours

		GROUP				Total
		A		B		
Grading of POST	0	30	100.0%	30	100.0%	60
Total		30	100.0%	30	100.0%	60

At 24 hours postoperatively, none of the patients reported POST in both the groups.

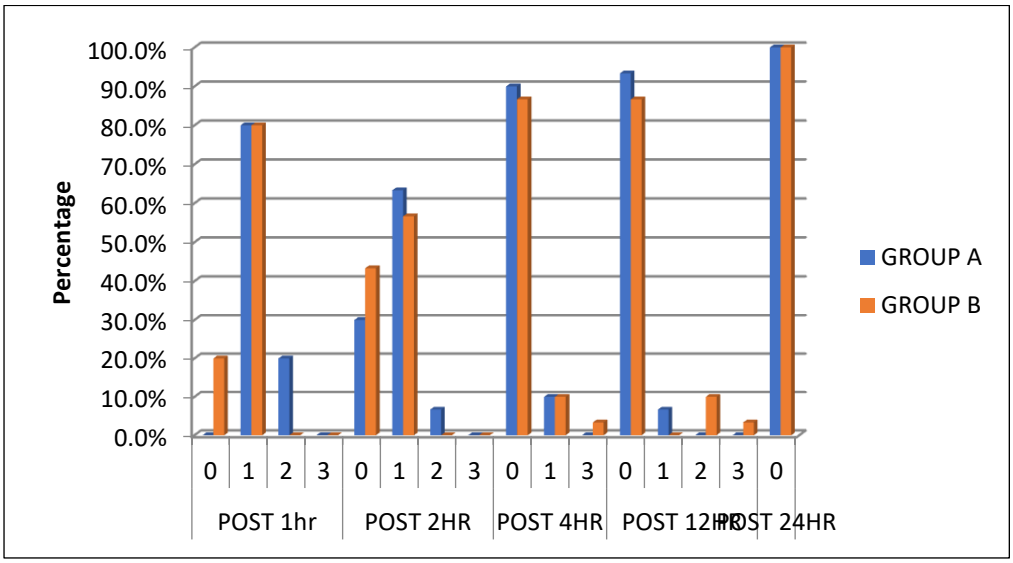


Figure 9: Incidence of Postoperative sore throat at various time intervals

D. NUMERICAL RATE SCORE (NRS)

Numerical Rating Scale (NRS), was marked from 0 to 10, where 0 means no sore throat and 10 means worst imaginable pain in throat. NRS was assessed post extubation at 1, 2, 4, 12 and 24 hours in Post anesthesia care unit.

Table 15: Incidence and severity of Numerical rating scale (NRS) at 1 hour

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
NRS Score (1hour)	4.37	1.87	3.00	1.26	0.002

Mean NRS of patients in group A was 4.37±1.87 and in group B was 3.0±1.26. The severity of NRS at 1 hour interval was significantly lower in group B as compare to group A (p-value = 0.002)

Table 16: Incidence and severity of Numerical rating scale (NRS) at 2 hour

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
NRS 2hour	2.60	1.94	1.72	1.22	0.035

The mean NRS for pain intensity at 2 hour was significantly higher in group A (Mean=2.60±1.94) as compared to group B (Mean=1.72±1.22), with a statistically significant difference between the two groups (p-value = 0.035) as demonstrated in table 16.

Table 17: Incidence and severity of Numerical rating scale (NRS) at 4 hour

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
NRS 4hour	1.07	1.62	0.67	1.99	0.024

Mean NRS scores were 1.07±1.62 and 0.67±1.99 for group A and group B, respectively at 4 hours. Postoperative pain intensity, as measured by NRS scores at 4 hours, was statistically higher in group A compared to group B, with a p-value of 0.024 as shown in table 17, suggesting increased severity of pain in group A in relation to group B.

Table 18: Incidence and severity of Numerical rating scale (NRS) at 12 hour

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
NRS 12hour	0.23	0.90	0.83	2.34	0.223

At the 12 hour postoperatively, in patients of group A, mean NRS score was 0.23±0.90 whereas, in group B, NRS score was 0.83±2.34.

A non-significant diversion in pain intensity was noted, with group A exhibiting lower NRS score in contrast to group B, with a p-value 0.223. Thus, the incidence and severity was similar between the two groups as depicted in table 18.

Table 19: Incidence and severity of Numerical rating scale (NRS) at 24 hour

	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
NRS 24hour	0.00	0.00	0.00	0.00	1.000

The mean NRS score was minimum (0) in both the groups at this interval of time. This implies incidence of NRS seems to be negligible at 24 hours postoperatively.

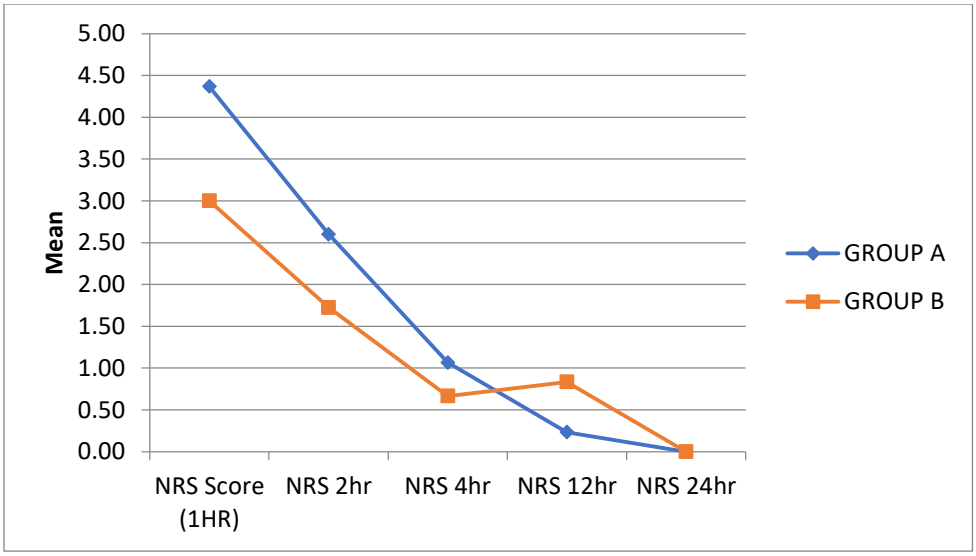


Figure 10: NRS between two groups at 1, 2, 4, 12, 24hours

E. INCIDENCE OF COUGHING

Cough incidence and severity score was assessed post-extubation at 0, 1, 2, 4, 12 and 24hours in PACU.

Table 20: Incidence of postoperative coughing at 0, 1, 2, 4, 12 and 24 hour

	GROUP A	GROUP B	Total	p-value
Incidence of cough	n=30	n=30		
0 hour	0 (0.0%)	3 (10.0%)	3	0.076
1 hour	11 (36.7%)	7 (23.3%)	18	0.399
2 hour	2 (6.7%)	3 (10.0%)	5	0.640
4 hour	0 (0.0%)	1 (3.3%)	1	0.313
12 hour	0 (0.0%)	1 (3.3%)	1	0.313
24 hour	0 (0.0%)	0 (0.0%)	0	

No significant difference was noted in the incidence of cough in the two groups at all the time intervals (Table 20).

F. SEVERITY OF COUGHING

Table 21: Severity of postoperative coughing at 0 hour

Grading of cough		GROUP				Total	p-value
		A		B			
0 hour	0	30	100.0%	27	90.0%	57	0.076
	1	0	0.0%	3	10.0%	3	
	2	0	0.0%	0	0.0%	0	
	3	0	0.0%	0	0.0%	0	

Grade 0 cough was seen in 100% of the patients in group A whereas it was reported in 90% of the patients in group B. Unlike group B, where 10% of the patients had grade 1 cough, no patients in group A experienced this level of cough severity. None of the patients in either group reported grade 2 or 3 cough. Therefore, the severity of coughing at 0 hour was similar in both the groups, with p-value 0.076 (Table 21).

Table 22: Severity of postoperative coughing at 1 hour

Grading of cough		GROUP				Total	p-value
		A		B			
1 hour	0	19	63.3%	23	76.7%	42	0.399
	1	11	36.7%	7	23.3%	18	
	2	0	0.0%	0	0.0%	0	
	3	0	0.0%	0	0.0%	0	

In group A, 63.3% of the patients had grade 0 cough whereas in group B, 76.7% of the patients reported grade 0 cough at 1 hour. Grade 1 cough was more common in group A, affecting 36.7% of the patients, compared to 23.3% in group B. No patients in either group A or B reported cough of grade 2 or 3. Therefore, the severity of postoperative cough at 1 hour was similar between the two groups, (p-value = 0.399) as illustrated in Table 22.

Table 23: Severity of postoperative coughing at 2 hour

Grading of cough		GROUP				Total	p-value
		A		B			
2 hour	0	28	93.3%	27	90.0%	55	0.640
	1	2	6.7%	3	10.0%	5	
	2	0	0.0%	0	0.0%	0	
	3	0	0.0%	0	0.0%	0	

The incidence of grade 0 cough was seen in 93.3% of the patients in group A and 90% of the patients in group B. Grade 1 cough was reported in 6.7% of the patients in group A whereas it is 10% in group B. There were no reports of grade 2 or 3 cough in either group A or group B indicating none of the patients in either group experienced moderate or severe cough symptoms. Thus, the severity of postoperative cough at 2 hour was similar in both the groups with p-value=0.640 (Table 23).

Table 24: Severity of postoperative coughing at 4 hour

Grading of cough		GROUP				Total	p-value
		A		B			
4 hour	0	30	100.0%	29	96.7%	59	0.313
	1	0	0.0%	1	3.3%	1	
	2	0	0.0%	0	0.0%	0	
	3	0	0.0%	0	0.0%	0	

Group A showed a 100% incidence of grade 0 cough (no cough), while group B had a 96.7% incidence of grade 0 cough. Notably, no patients in group A reported grade 1 cough whereas 3.3% of the patients in group B experienced mild cough symptoms (grade 1). Neither group had any instances of moderate (grade 2) or severe (grade 3) cough. Therefore, the severity of postoperative cough at 4 hour was similar among the two groups (p-value= 0.313, Table 24)

Table 25: Severity of postoperative coughing at 12 hour

Grading of cough		GROUP				Total	p-value
		A		B			
12 hour	0	30	100.0%	29	96.7%	59	0.313
	1	0	0.0%	1	3.3%	1	
	2	0	0.0%	0	0.0%	0	
	3	0	0.0%	0	0.0%	0	

At the 12 hour postoperative interval, a complete absence of cough symptoms (grade 0) was observed in all of the patients in group A (100%) and almost all patients in group B (96.7%). Meanwhile, no patients in group A experienced grade 1 cough whereas 3.3% of the patients in group B had grade 1 cough. Neither group reported any moderate (grade 2) or severe (grade 3) cough symptoms. Thus, the severity of postoperative cough at 12 hour was similar in both the groups with p-value= 0.313 (Table 25).

Table 26: Severity of postoperative coughing at 24 hour

Grading of cough		GROUP				Total
		A		B		
24 hour	0	30	100.0%	30	100.0%	60

None of the patients in both the groups experienced cough at 24 hours postoperatively. The grade of cough was minimum at this interval of time.

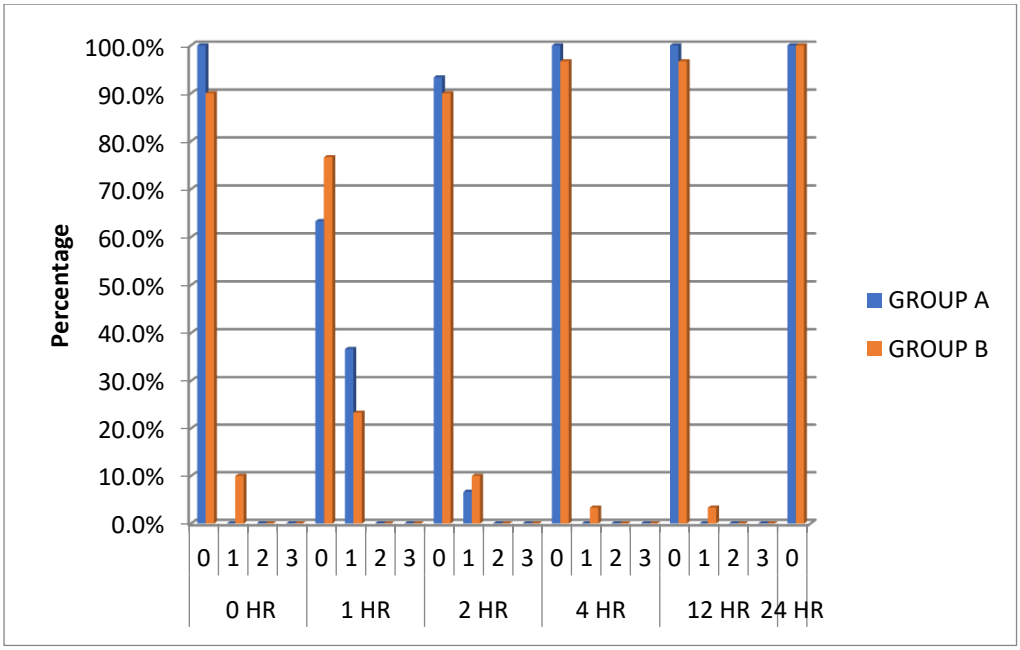


Figure 11: Incidence of postoperative cough between the two groups at 0, 1, 2, 4, 12 and 24 hours

DISCUSSION

Post-operative sore throat (POST) after general anesthesia is a major concern for all the anesthesiologists in the postoperative period due to its high occurrence rate.[58,59,60] It is ranked amongst the top ten undesirable outcomes following anesthesia.[50] POST still exists despite extensive efforts made over the years. Tracheal intubation is frequently complicated by postoperative sequelae of sore throat, cough and hoarseness, which constitute a common and distressing constellation of symptoms that can significantly impede patient comfort[3] and recuperation. Despite the fact that it can impede patient recovery and potentially raise healthcare costs,[1] only a limited number of research articles on airway complications have studied POST.

The potential causes of sore throat are believed to be irritation, mechanical trauma and inflammation due to the insertion of endotracheal tube (ETT) and cuff inflation.[61] It is particularly prevalent following surgeries of long duration. In the present study, patient underwent two position changes to achieve the prone position and recover from anaesthesia at the end of surgery. Additionally, the prone position was maintained throughout the surgery. These factors might have contributed to the development of postoperative sore throat. A study conducted by Toshiyuki et al[13] reported a high incidence of endotracheal tube displacement and cuff pressure fluctuations when patients were repositioned from supine to prone, with 91.7% experiencing the tube movement and 86.3% exhibiting the cuff pressure changes. These alterations subsequently influenced the development and severity of POST.

The coughing and sore throat triggered by the endotracheal tube can complicate emergence[62] from general anesthesia, potentially causing dangerous hyperdynamic responses in the postoperative period. The responses encompass tachycardia, hypertension, dysrhythmia, raised intraocular pressure, increased intracranial pressure, wound dehiscence, and bronchospasm.[63] It has been widely recorded that coughing and its consequences can be detrimental to the patients.

Various analgesics and anti-inflammatory drugs, administered topically, locally or systemically, have been utilized to lessen the frequency and intensity of postoperative sore throat (POST). Research suggests that employing a multi modal strategy comprising non-pharmacological and pharmacological interventions can mitigate postoperative sore throat (POST). Non-pharmacologic approaches include preffering a supraglottic airway device[64] over a tracheal tube, employing a smaller diameter tube, avoiding cuff over inflation, and utilizing gentle oropharyngeal suctioning. Various pharmacologic agents for POST such as lidocaine, corticosteroids, ketamine, magnesium, and benzydamine have been utilized to varying degree of success.

Aspirin, classified as an NSAID, undergoes rapid conversion in the body to salicylic acid with a half-life of 8-12 hours[65] for the anti-inflammatory dose. These actions are facilitated by the suppression of prostaglandin system. Aspirin gargle has been documented to effectively alleviate pain associated with oral lesions.[66] Moreover, studies suggest that aspirin administration may reduce the severity of POST following tracheal intubation.[27] By harnessing its potent analgesic and anti-inflammatory effects, aspirin effectively diminishes the pain and discomfort associated with POST, thereby substantially enhancing patient comfort and overall satisfaction during the postoperative period.

Magnesium has a diverse range of uses, such as acting as a membrane stabilizer, controlling severe asthma, managing eclampsia in pregnancy and serving as an NMDA blocker for acute and chronic pain. Magnesium exerts its analgesic action by acting as a non-competitive blocker of NMDA receptor in a voltage-dependent manner. Magnesium diminishes the activation of C-fibers by hindering the slow excitatory postsynaptic currents generated by NMDA receptor activation. The NMDA receptor antagonist eliminates the influx of calcium and sodium into cells thereby halting central sensitization and wind-up associated with peripheral nociceptive stimulation. The use of preoperative magnesium gargles has proven to be a highly effective strategy in minimizing the severity of POST.[15,67] Recent findings on

the occurrence of postoperative sore throat after anesthesia have suggested that the incidence of POST may not solely be attributed to damage from the tracheal tube cuff but rather to increased muscle contracture.[68] A prospective study conducted by Yadav et al, evaluated the effect of magnesium sulphate nebulization on POST at rest and swallowing and found that it significantly reduced the incidence of POST.[33] By leveraging magnesium's robust anti-inflammatory and muscle relaxant properties, these gargles successfully reduce throat inflammation, spasms, and discomfort, paving the way for a smoother and more comfortable recovery. Additionally, magnesium's analgesic effects and ability to suppress coughing further contribute to a significant decrease in POST severity, ultimately enhancing patient satisfaction and overall wellbeing.

In our study, we selected aspirin and magnesium sulphate as comparators because aspirin is a widely used, cost-effective and over the counter medication and is shown to be effective in preventing POST. Furthermore, magnesium sulphate has been evaluated against various agents, including ketamine and dexamethasone, but its comparative effectiveness with aspirin has only been investigated in a single study. Therefore, in our study we compared the efficacy of aspirin and magnesium sulphate for prevention of POST. We opted for the gargling route, as it is a convenient and time saving option for the patients.

I. DEMOGRAPHIC PROFILE

In our study, the demographic characteristics which include age, sex, height, weight, BMI, ASA physical status and duration of anaesthesia were comparable between both the groups. The demographic profile can have a bearing on the incidence and severity of POST. A study published by Jaensson et al investigated gender differences in the development of POST following endotracheal intubation and found that female patients are more likely to experience POST compared to males[4]. Patel et al[61] and Mondal et al[68] had also studied the incidence of sore throat and showed a comparable distribution of these

demographic parameters. The duration of anaesthesia is a significant factor, as a longer duration of surgery has been linked to a higher likelihood of developing POST[60]. A prospective study conducted by Ahmed et al, showed a direct correlation between the prolonged surgical time and an increased risk of POST[69]. Endotracheal tube cuff pressures were monitored intra-operatively at 30 minutes interval, and maintained between 22-25 cm of H_2O, if found to be increased. We found that the cuff pressures were similar among both the groups. It is important to keep the ETT cuff pressure low as the evidence suggests that limiting the ETT cuff pressures will decrease the incidence of POST[70]. According to the study conducted by Kovacevic et al, monitoring and adjustment of ETT cuff pressure reduces POST[71].

II. INCIDENCE AND SEVERITY OF POST

The findings of present study suggest that group B (Magnesium sulphate) had reduced incidence of POST as compared to group A (Aspirin) at 1 hour (p-value=0.010). However, at 2, 4, and 12 hours postoperatively, the incidence of POST was comparable between the two groups (p-values <0.05). The severity of POST was also significantly lower in magnesium group at 1 hour (p-value=0.002). However, at 2, 4 and 12 hours the severity of POST was similar among the two groups. None of the patients in either of the groups experienced POST at 24 hours postoperatively. The grade of POST was minimum at this interval of time.

Our findings are in concordance with Gupta et al[33] who reported the effectiveness of preoperative nebulization of magnesium sulphate in decreasing in the incidence and severity of POST at rest and on swallowing at all points. The authors described that the reduction in postoperative sore throat (POST) may be attributed to a localized reduction in inflammation, resulting from magnesium's anti-inflammatory properties. This decrease in inflammation is likely due to magnesium's ability to suppress the release of pro-inflammatory mediators, such as histamine, thromboxanes, and leukotrienes, which contributes to the inflammatory response.

Our findings are also in agreement with the study by Rajan et al[52], who reported a reduced incidence of POST in magnesium group (M1) at 0, 2, and 4 hours after extubation. Consistent with our findings, Borazen et al[34] conducted a randomized study on the use of oral magnesium lozenges for reducing postoperative sore throat. Their results showed that the magnesium group had significantly lower severity scores for postoperative sore throat at 0 and 2 hours compared to control group. A study by Teymourian et al[49], found that gargling with magnesium sulphate reduces sore throat and pain more effectively than ketamine. A systematic review and meta-analysis by Kuriyama et al[72] concluded that there is sufficient evidence to support the use of topical magnesium as an effective measure against POST.

A study conducted by Aggarwal et al[28] found that gargling with aspirin and benzydamine effectively decreased the incidence and severity of POST. Specifically, aspirin gargle demonstrated efficacy in reducing POST at 2 hours postoperatively, while benzydamine gargle showed showed sustained efficacy for up to 24 hours. In a 2014 meta-analysis of 11 RCTs, Kalil et al[73] evaluated the effectiveness of non-steroidal and non-local anesthetic topical medications in preventing POST. Their review identified aspirin and ketamine gargles as the promising interventions, suggesting a potential benefit for reducing incidence and severity of POST.

A separate investigation conducted by Chattopadhyay et al[27] comparing the efficacy of magnesium and aspirin gargle, revealed a significant association between magnesium administration and decreased incidence of postoperative sore throat. The incidence and severity of POST was effectively reduced in magnesium group at 0, 2 and 4 hour. However, at 6, 9, 12 and 16 hours the difference in both the groups were similar.

III. NUMERICAL RATE SCORE(NRS)

In our study, we have found that NRS Score was significantly reduced in group B in comparison to group A at 1, 2 and 4 hour respectively and the difference was statistically significant. Whereas at 12 hour, NRS

was comparable between both the groups. NRS score was minimum in both the groups at 24 hours postoperatively. Thus, the incidence of NRS seems to be negligible at 24 hours interval of time.

Chattopadhyay et al[27] also observed that the visual analogue score (VAS) for pain was significantly less in magnesium as compared to aspirin group at all time points.

In our study, at all the time points, NRS was less than 5 among both the groups. A randomized study by Park et al[32] found that the VAS scores for POST severity were comparable between the magnesium sulphate and dexamethasone groups at all time points, indicating similar efficacy in reducing POST severity.

IV. INCIDENCE OF COUGHING

Cough was assessed post extubation at 0, 1, 2, 4, 12 and 24 hours in PACU.

Our analysis revealed a similar distribution of postoperative coughing events between the aspirin and magnesium group at various time intervals (0, 2, 4 and 12 hours). While a subtle reduction in cough incidence was noted in the magnesium group compared to the aspirin group at 1 hour, this difference did not reach statistical significance. Notably, both the groups demonstrated a complete resolution of coughing by the 24 hours interval. These findings suggest that both the aspirin and magnesium sulphate exhibit similar efficacy in reducing postoperative coughing, with no significant differences observed between the two treatment groups. Consistent with our findings, a study by Rajan S et al.[52] also reported no statistically significant differences in postoperative cough among all the three study groups, up to 24 hours postoperatively, suggesting a similar outcome in terms of cough incidence.

ADVERSE EFFECTS

Both the drugs, aspirin and magnesium sulphate were found to have good safety profile, with no reported side effects.

LIMITATIONS

There are certain limitations in our study which are worth mentioning:

1. Patients with anticipated difficult airway were excluded, thus narrowing the clinical profile. A larger clinical trial which includes patients with anticipated difficult airway may be planned to address this limitation.
2. The assessment of POST relied on the subjective scale, which may be vulnerable to bias and potentially influenced by individual perspectives, potentially impacting the accuracy and reliability of the results.
3. All intubations were performed by a highly experienced anesthesiologist, aiming to reduce tissue trauma to a minimum. However, this may be difficult to achieve in day to day practice wherein, anaesthesiologists of varying experiences intubating the patients. It remains to be seen whether the findings of this study can be replicated under such conditions.

SUMMARY AND CONCLUSION

The present study was conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after approval from ethics committee. Sixty adult patients of ASA grade I, II and III, between 18 to 65 years of age, of either sex posted for elective lumbar laminectomy surgery under general anaesthesia were enrolled for this prospective, double blinded and randomized control trial. Patients were randomly allocated into two groups of 30 patients each.

In Group A, tab Aspirin 325mg was dissolved in 20 ml of 5% dextrose.

In Group B, 2 ml of Magnesium sulphate 50% w/v was dissolved in 20 ml of 5% dextrose.

Patients in both the groups were instructed to gargle the study solution for 30 seconds, 15 minutes before induction of anesthesia. The anaesthetic technique was standardized in all the study groups. Intraoperatively, ETT cuff pressure was measured every 30 minutes and maintained between 22-25 cm of H_2O by deflating the cuff if required. After the completion of surgery, the patient was extubated and shifted to the post anaesthesia care unit (PACU) for further care and observation.

In PACU, following parameters were observed:

Incidence and Severity of POST and NRS score at 1, 2, 4, 12 and 24 hours and post-operative cough was assessed at 0, 1, 2, 4, 12 and 24 hours.

The following conclusions were drawn:

- The patients in both the groups were comparable with respect to age, sex, weight, height, BMI, ASA physical status, duration of anaesthesia.
- The endotracheal cuff pressure measured was comparable in both the groups.
- Incidence of POST was significantly lower in magnesium sulphate group as compared to aspirin at 1 hour postoperatively whereas it was found to be similar at 2, 4, 12 and 24 hours.

- Severity of POST was significantly lower in magnesium sulphate group as compared to aspirin at 1 hour postoperatively. However, it was found to be similar at 2, 4, 12 and 24 hours.
- NRS score for throat pain was significantly lower at 1, 2 and 4 hour in the magnesium group whereas it was comparable in both the groups at 12 and 24 hours.
- Incidence and severity of cough was similar at all the time intervals.

Hence, we conclude that magnesium sulphate gargles are more effective than aspirin in the early hours of postoperative period for reducing the incidence and severity of POST. In accordance with our study, both the drugs, aspirin and magnesium sulphate can be used safely for the prevention of postoperative sore throat.

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S. No	MRD No	INITIAL NAME	GROUP	AGE (Yrs)	GENDER	DIAGNOSIS	HEIGHT (cm)	WEIGHT (Kg)	BMI (Kg/m2)	ASA Grade	DATE OF SURGERY	SURGERY PERFORMED	TIME OF GARGLING	ANESTHESIA START TIME	TIME OF INTUBATION	TIME OF EXTUBATION	TIME OF SHIFTING TO PACU	DURATION OF ANESTHESIA (IN MIN)
1	403324	HS	B	37	Male	L4L5 PIVD	177	103	32.6	II	10/17/2022	Lumbar laminectomy	9:15	9:30	9:40	12:10	12:25	160
2	366600	GK	B	45	Male	L5S1 PIVD	176	80	25.8	I	10/29/2022	Lumbar laminectomy	10:00	10:15	10:20	12:30	1:00	135
3	1405336	HR	B	67	Male	L4L5 PIVD	182	80	24.2	II	10/31/2022	Lumbar laminectomy	9:30	9:45	9:52	1:10	1:20	205
4	1285693	SS	B	50	Male	T12L1 Cord compression	180	75	23.1	III	11/2/2022	Lumbar laminectomy	9:10	9:15	9:23	12:00	12:15	165
5	1407528	PK	B	50	Female	L3L4 PIVD	167	71	25.5	II	11/3/2022	Lumbar laminectomy	8:45	8:52	9:00	1:05	1:20	255
6	1426888	OS	A	44	Male	Cauda equina syndrome	173	75	25.1	II	12/5/2022	Lumbar laminectomy	8:30	8:45	9:10	12:00	12:15	195
7	208976	RS	B	53	Male	L4L5 PIVD	176	75	24.2	II	12/5/2022	Lumbar laminectomy	9:25	9:40	9:50	1:10	1:30	210
8	1403322	CS	B	52	Male	Lumbar canal stenosis	170	79	27.3	II	12/5/2022	Lumbar laminectomy	9:45	9:52	10:00	1:00	1:20	190
9	1431795	JK	A	55	Female	PIVD	161	74	28.5	III	12/7/2022	Lumbar laminectomy	9:15	9:30	9:37	12:45	1:00	195
10	1455667	SS	A	55	Male	Lumbar canal stenosis	170	78	27	III	12/15/2022	Lumbar laminectomy	8:30	8:45	8:48	12:30	12:45	225
11	1462163	SS	A	59	Female	PIVD	167	74	26.5	II	12/15/2022	Lumbar laminectomy	9:45	10:00	10:08	12:15	12:30	135
12	1433809	KS	A	52	Male	PIVD	192	120	32.6	II	12/19/2022	Lumbar laminectomy	9:15	9:30	9:38	12:30	1:05	190
13	1435852	RS	A	58	Male	L5S1 PIVD	179	85	26.5	II	12/23/2022	Lumbar laminectomy	8:50	9:10	9:17	1:00	1:10	230
14	1437095	KK	A	32	Female	PIVD	161	65	25.1	I	12/26/2022	Lumbar laminectomy	8:50	9:05	9:12	12:45	1:00	220
15	1436621	VD	B	55	Female	L4L5 PIVD	161	58	22.4	I	12/27/2022	Lumbar laminectomy	9:00	9:08	9:15	12:30	12:44	200
16	1423464	SK	A	62	Female	L4L5 PIVD	167	83	29.8	II	12/28/2022	Lumbar laminectomy	9:00	9:15	9:20	1:10	1:20	235
17	1479585	DS	A	36	Male	L5S1 PIVD	176	96	31	II	1/5/2023	Lumbar laminectomy	8:15	8:30	8:40	11:10	11:30	160
18	1441835	KS	A	60	Male	L3L4 PIVD	176	74	23.9	II	1/6/2023	Lumbar laminectomy	8:45	9:00	9:08	12:15	12:38	195
19	1444756	KB	B	31	Male	L4L5 PIVD	182	95	28.7	II	1/1/2023	Lumbar laminectomy	8:45	9:00	9:07	1:00	1:20	250
20	1450549	BS	A	37	Male	L5S1 PIVD	164	68	25.3	II	1/25/2023	Lumbar laminectomy	8:45	9:00	9:07	1:00	1:20	240
21	1427103	JK	B	52	Female	Lumbar canal stenosis	164	76	28.3	II	1/28/2023	Lumbar laminectomy	8:45	9:00	9:10	1:30	1:40	280
22	1431533	DS	B	58	Male	L4L5 PIVD	176	76	24.5	II	2/3/2023	Lumbar laminectomy	8:55	9:10	9:18	1:15	1:35	245
23	1091697	HK	A	38	Female	L4L5 PIVD	161	75	28.9	III	2/9/2023	Lumbar laminectomy	9:00	9:10	9:17	12:50	1:10	220
24	1431693	SS	B	38	Male	L4L5 PIVD	173	90	30.1	III	2/14/2023	Lumbar laminectomy	8:50	9:05	9:18	12:35	1:00	210
25	422586	HK	A	62	Male	PIVD	182	120	36.2	II	2/21/2023	Lumbar laminectomy	8:45	9:00	9:10	3:15	3:30	375
26	1466863	KS	B	29	Male	PIVD	179	82	25.6	II	2/22/2023	Lumbar laminectomy	8:45	9:00	9:08	12:30	12:50	210
27	1471889	RR	B	65	Female	PIVD	158	85	34	II	3/1/2023	Lumbar laminectomy	9:30	9:45	9:54	1:00	1:10	195
28	1473430	HK	A	39	Female	PIVD	167	70	25.1	II	3/11/2023	Lumbar laminectomy	9:00	9:15	9:20	1:00	1:15	225
29	374319	GK	B	53	Female	L3L4 PIVD	158	68	27.2	III	3/13/2023	Lumbar laminectomy	8:30	8:45	8:56	12:50	1:00	245
30	1479934	HS	A	50	Male	L4L5S1 PIVD	170	70	24.2	II	3/14/2023	Lumbar laminectomy	9:30	9:45	9:50	1:30	1:45	225
31	1136589	KK	B	49	Female	L4L5 PIVD	167	71	25.5	II	3/15/2023	Lumbar laminectomy	9:30	9:45	9:52	1:30	1:45	225
32	1474918	HS	B	48	Male	L2L3 PIVD	173	65	21.7	III	3/15/2023	Lumbar laminectomy	8:45	9:00	9:10	12:05	12:20	185
33	6993	SK	B	45	Male	lumbar PIVD	167	65	23.3	II	3/27/2023	Lumbar laminectomy	8:15	8:30	8:37	11:15	11:30	165
34	1468431	KK	A	54	Female	L4L5PIVD	176	74	23.9	II	3/28/2023	Lumbar laminectomy	8:50	9:10	9:18	12:30	1:00	200
35	7381	J	B	34	Male	L4L5PIVD	176	85	27.4	II	4/19/2023	Lumbar laminectomy	9:30	9:45	9:54	1:00	1:15	195
36	199608	KK	A	60	Female	Lumbar canal stenosis	167	74	26.5	II	4/25/2023	Lumbar laminectomy	8:45	9:00	9:10	12:00	12:20	180
37	1509076	JS	B	28	Male	L5S1 PIVD	173	85	28.4	II	5/2/2023	Lumbar laminectomy	8:30	8:45	8:54	12:15	12:35	210
38	1507971	BS	B	42	Male	Cauda equina syndrome	179	78	24.3	I	5/2/2023	L5S1Laminectomy	8:50	9:05	9:12	12:30	12:50	205
39	1498829	BS	A	73	Male	L4L5PIVD	180	103	31.8	II	4/5/2023	Lumbar laminectomy	8:45	9:00	9:08	12:10	12:20	190
40	1115763	RK	A	61	Female	L4L5PIVD	158	60	24	II	5/9/2023	Lumbar laminectomy	8:45	9:00	9:10	12:15	12:35	195
41	1514403	SG	B	58	Female	Lumbar canal stenosis	164	66	24.5	II	5/11/2023	Lumbar laminectomy	8:45	9:00	9:08	12:15	12:30	195
42	1513069	DS	A	37	Male	L4L5PIVD	170	80	27.7	II	5/24/2023	Lumbar laminectomy	8:50	9:05	9:15	12:30	12:45	205
43	1526884	KD	B	72	Female	Lumbar canal stenosis	158	85	34	III	6/1/2023	Lumbar laminectomy	8:45	9:00	9:08	12:30	12:45	210
44	1572778	AD	A	55	Female	Lumbar canal stenosis	167	80	28.7	III	8/21/2023	Lumbar laminectomy	9:00	9:15	9:25	12:30	12:45	195
45	1577782	SK	B	51	Male	lumbar PIVD	170	68	23.5	II	8/28/2023	Lumbar laminectomy	8:30	8:45	8:55	12:00	12:15	195
46	1579616	DS	A	38	Male	Lumbar canal stenosis	176	74	23.9	II	8/29/2023	Lumbar laminectomy	8:15	8:30	8:40	11:45	12:10	195
47	1584330	NG	A	30	Female	L4L5PIVD	170	60	20.8	II	9/6/2023	Lumbar laminectomy	8:40	9:00	9:10	12:15	12:30	195
48	1593386	B	A	55	Female	lumbar PIVD	170	64	22.1	III	9/25/2023	Lumbar laminectomy	8:30	8:45	8:54	12:00	12:15	195
49	1595636	HK	B	34	Female	Lumbar canal stenosis	167	68	24.4	II	9/25/2023	Lumbar laminectomy	8:50	9:00	9:10	12:30	12:45	210
50	1599242	HR	B	26	Male	Lumbar canal stenosis	176	74	23.9	II	9/30/2023	Lumbar laminectomy	8:50	9:05	9:13	12:30	12:45	205
51	1597845	GJ	A	27	Male	lumbar PIVD	170	68	23.5	I	10/3/2023	Lumbar laminectomy	8:45	9:00	9:08	12:00	12:30	180
52	1587848	GK	A	58	Female	Lumbar canal stenosis	164	64	23.8	II	10/6/2023	Lumbar laminectomy	8:30	8:45	8:55	1:00	1:30	255
53	1543847	RW	B	38	Male	lumbar PIVD	170	72	24.9	II	10/7/2023	Lumbar laminectomy	8:45	9:00	9:10	12:00	12:15	180
54	1609091	KK	A	62	Female	Lumbar canal stenosis	167	60	21.5	II	10/17/2023	Lumbar laminectomy	8:50	9:10	9:18	12:30	12:45	200
55	1604246	SK	A	53	Male	Lumbar canal stenosis	170	70	24.2	III	10/18/2023	Lumbar laminectomy	8:15	8:30	8:40	11:30	12:00	180
56	7717	RK	A	65	Male	Lumbar canal stenosis	170	75	26	III	10/28/2023	Lumbar laminectomy	8:30	8:45	8:53	12:30	1:00	225
57	1610410	KY	B	50	Male	Lumbar canal stenosis	164	64	23.8	II	10/30/2023	Lumbar laminectomy	9:00	9:15	9:25	12:30	1:00	195
58	1615524	AK	A	52	Male	Lumbar canal stenosis	173	72	24.1	II	10/31/2023	Lumbar laminectomy	9:00	9:15	9:24	1:15	1:30	240
59	1620194	JK	B	62	Female	Lumbar canal stenosis	167	65	23.3	III	11/14/2023	Lumbar laminectomy	8:30	8:45	8:50	11:45	12:00	180
60	426962	KK	B	55	Female	Lumbar canal stenosis	164	66	24.5	II	11/22/2023	Lumbar laminectomy	9:00	9:15	9:25	1:00	1:30	225

S. No	MRD No	INTRAOPERATIVE ENDOTRACHEAL CUFF PRESSURE (cmH2O)						GRADING OF POST					NUMERICAL RATING SCALE (NRS) SCORE					GRADING OF COUGH						COUGH	ADVERSE EFFECTS
		At 30min	At 60min	At 90min	At 120min	At 150min	At 180min	At 1 HR	At 2 HR	At 4 HR	At 12 HR	At 24 HR	At 1 HR	At 2 HR	At 4 HR	At 12 HR	At 24 HR	At 0 HR	At 1 HR	At 2 HR	At 4 HR	At 12 HR	At 24 HR		
1	403324	24	22	24	22	24	24	1	1	1	0	0	2	2	1	1	0	0	0	0	1	0	0	Yes	No
2	366600	24	22	24	24	24	24	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	Yes	No
3	1405336	22	24	24	22	24	24	1	0	0	0	0	3	1	0	0	0	0	0	0	0	0	0	No	No
4	1285693	24	22	22	24	24	24	1	1	0	2	0	1	1	0	5	0	0	0	1	0	0	0	Yes	No
5	1407528	24	24	22	22	24	24	1	1	3	3	0	5	4	10	10	0	0	0	0	0	0	0	No	No
6	1426888	22	24	24	24	22	-	1	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No
7	208976	24	24	22	24	24	24	1	0	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No
8	1403322	22	24	24	22	24	24	1	0	0	2	0	2	1	0	2	0	0	0	0	0	1	0	Yes	No
9	1431795	24	22	24	22	24	24	1	1	0	0	0	3	1	0	4	0	0	0	0	0	0	0	No	No
10	1455667	24	24	24	24	24	24	1	1	0	0	0	5	3	1	0	0	0	0	0	0	0	0	No	No
11	1462163	24	24	24	24	24	24	2	1	0	0	0	5	3	3	0	0	0	0	0	0	0	0	No	No
12	1433809	24	22	24	22	24	24	1	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No
13	1435852	24	24	22	24	22	24	1	1	0	0	0	5	3	1	0	0	0	0	0	0	0	0	No	No
14	1437095	22	24	22	24	24	24	1	0	0	0	0	4	2	0	0	0	0	0	0	0	0	0	No	No
15	1436621	24	22	24	24	24	24	1	1	1	0	0	4	3	3	0	0	0	0	0	0	0	0	No	No
16	1423464	24	22	24	24	24	24	1	1	0	0	0	2	0	0	0	0	0	1	0	0	0	0	Yes	No
17	1479585	24	22	24	24	22	-	1	0	0	0	0	3	3	2	0	0	0	0	0	0	0	0	No	No
18	1441835	22	24	22	24	22	24	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	No	No
19	1444756	24	22	22	24	24	24	1	1	0	0	0	3	2	1	0	0	0	0	0	0	0	0	No	No
20	1450549	24	22	24	24	22	24	1	1	0	0	0	5	3	2	0	0	0	1	0	0	0	0	Yes	No
21	1427103	24	22	24	24	24	24	1	1	0	2	0	3	3	0	7	0	0	1	0	0	0	0	Yes	No
22	1431533	24	22	24	24	24	24	1	0	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No
23	1091697	22	24	24	22	24	24	1	1	0	0	0	4	3	2	0	0	0	0	0	0	0	0	No	No
24	1431693	24	22	24	24	24	24	1	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	No	No
25	422586	24	24	22	24	24	24	2	2	1	1	0	10	10	8	3	0	0	0	0	0	0	0	No	No
26	1466863	22	24	24	24	24	24	1	1	1	0	0	5	4	4	0	0	0	1	0	0	0	0	Yes	No
27	1471889	24	24	24	22	24	24	1	1	0	0	0	4	3	1	0	0	0	1	0	0	0	0	Yes	No
28	1473430	24	24	24	22	24	24	1	1	0	0	0	4	3	2	0	0	0	1	0	0	0	0	Yes	No
29	374319	24	24	22	24	24	24	0	1	0	0	0	3	2	0	0	0	0	1	0	0	0	0	Yes	No
30	1479934	24	22	24	24	24	24	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	No	No
31	1136589	24	22	24	24	24	24	1	1	0	0	0	4	4	0	0	0	0	0	0	0	0	0	No	No
32	1474918	22	24	24	22	24	-	0	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No
33	6993	24	22	24	24	24	-	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	No	No
34	1468431	24	24	24	24	24	22	1	1	0	0	0	4	4	1	0	0	0	1	0	0	0	0	Yes	No
35	7381	24	22	24	24	24	24	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	Yes	No
36	199608	24	24	22	24	24	22	2	2	1	0	0	8	4	2	0	0	0	1	0	0	0	0	Yes	No
37	1509076	24	24	24	24	24	22	1	1	0	0	0	3	1	0	0	0	0	0	0	0	0	0	No	No
38	1507971	22	24	24	24	24	24	1	1	0	0	0	2	1	0	0	0	0	0	0	0	0	0	No	No
39	1498829	24	24	22	24	24	24	1	1	0	0	0	5	4	2	0	0	0	0	1	0	0	0	Yes	No
40	1115763	22	24	24	22	24	24	2	1	1	0	0	5	4	2	0	0	0	1	0	0	0	0	Yes	No
41	1514403	24	24	22	24	24	24	1	1	0	0	0	3	2	0	0	0	1	0	0	0	0	0	Yes	No
42	1513069	22	24	22	22	24	24	1	0	0	0	0	4	2	0	0	0	0	0	0	0	0	0	No	No
43	1526884	24	24	22	24	24	24	1	0	0	0	0	4	-	0	0	0	0	1	0	0	0	0	Yes	No
44	1572778	22	24	24	24	24	24	1	0	0	0	0	4	2	1	0	0	0	0	0	0	0	0	No	No
45	1577782	22	24	24	24	24	24	1	1	0	0	0	5	2	0	0	0	0	0	1	0	0	0	Yes	No
46	1579616	24	24	24	24	24	-	2	1	0	0	0	7	4	1	0	0	0	1	0	0	0	0	Yes	No
47	1584330	24	24	24	22	24	24	1	0	0	0	0	4	2	0	0	0	0	0	0	0	0	0	No	No
48	1593386	22	24	24	24	24	-	1	1	0	0	0	4	0	0	0	0	0	1	1	0	0	0	Yes	No
49	1595636	24	22	24	24	24	22	1	0	0	0	0	4	2	0	0	0	0	0	0	0	0	0	No	No
50	1599242	22	24	24	24	24	24	1	1	0	0	0	5	2	0	0	0	0	0	1	0	0	0	Yes	No
51	1597845	24	24	24	22	24	22	1	0	0	0	0	3	0	0	0	0	0	1	0	0	0	0	Yes	No
52	1587848	24	22	24	24	24	24	1	1	0	0	0	4	2	0	0	0	0	0	0	0	0	0	No	No
53	1543847	24	24	24	24	24	-	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	No	No
54	1609091	22	24	24	24	24	-	2	1	0	0	0	7	4	2	0	0	0	1	0	0	0	0	Yes	No
55	1604246	22	24	24	22	24	-	1	0	0	1	0	4	2	0	0	0	0	0	0	0	0	0	No	No
56	7717	22	24	24	24	24	24	1	1	0	0	0	5	4	0	0	0	0	1	0	0	0	0	Yes	No
57	1610410	22	24	24	24	22	-	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	No	No
58	1615524	22	24	24	24	24	24	1	1	0	0	0	5	2	0	0	0	0	0	0	0	0	0	No	No
59	1620194	24	22	24	24	24	-	1	0	0	0	0	4	0	0	0	0	0	1	0	0	0	0	Yes	No
60	426962	24	24	24	24	24	24	1	1	0	0	0	3	2	0	0	0	0	0	0	0	0	0	No	No

Baba Farid University
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No. BFUHS/2K23p-TH/ 13148 Date 27/12/23

The Principal
Dayanand Medical College & Hospital
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Subject:: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 25.09.2023 has approved the plan of thesis of **Jaspal Kaur**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Comparative evaluation of aspirin and magnesium sulphate gargles for prevention of postoperative sore throat in patients undergoing lumbar laminectomy .

Supervisor
Dr. Sandeep Kundra
Professor
Dept. of Anaesthesiology

Co-Supervisor:-
Dr. Richa Jain
Assoc. Professor
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The student may submit the thesis in triplicate alongwith the plan in triplicate also, to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She may be directed to attach a photocopy of this letter with the forwarding letter while submitting thesis in the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic, if any.

Controller of Examinations

Note :

1. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED IN

PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MD

In

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

AUGUST, 2022 **DR JASPAL KAUR**

DEPARTMENT OF ANAESTHESIOLOGY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
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ABSTRACT OF PLAN OF THESIS

Title	Comparative evaluation of aspirin and magnesium sulphate gargles for prevention of postoperative sore throat in patients undergoing lumbar laminectomy.
For the degree of	MD Anaesthesia
Name of the candidate	Dr Jaspal Kaur
Supervisor	Dr. Sandeep Kundra, Professor, Department of Anaesthesia, DMCH, Ludhiana
Co-Supervisor	Dr. Richa Jain, Associate Professor, Department of Anaesthesia , DMCH, Ludhiana
Institution	Dayanand Medical College and Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Postoperative sore throat (POST) is a common complication after endotracheal intubation. POST contributes to discomfort and morbidity for the patient. POST is the result of local tissue trauma due to laryngoscopy and endotracheal intubation leading to the inflammation of the pharyngeal mucosa. Aspirin is a commonly used NSAID which acts by inhibiting the prostaglandin system. Aspirin gargles have been observed to significantly reduce the incidence and severity of POST. Magnesium, an NMDA receptor antagonist in a few preliminary studies has also been seen to reduce POST. However; definitive evidence on the role of magnesium sulphate gargles for the prevention of POST is lacking.

Aim of Study: To compare the efficacy of gargles with aspirin and magnesium sulphate for the prevention of postoperative sore throat in patients undergoing lumbar laminectomy in prone position.

Materials & methods: A prospective, randomized, double blinded study will be conducted on sixty patients of either sex between age group 18 to 65 years belonging to ASA grade I, II and III scheduled for elective lumbar laminectomy under general anaesthesia. Patients will be randomly allocated to two groups –Group A and Group B of 30 patients each. Group A patients will receive gargle solution of tab Aspirin 325mg in 20ml of 5% dextrose while group B patients will receive gargle solution of 2ml Magnesium sulphate in 20ml of 5% dextrose. In Post anesthesia care unit (PACU), patients will be evaluated for incidence and severity of sore throat using Numerical Rating Scale (NRS) and severity grading scale at 1, 2, 4,12 and 24 hrs postoperatively.

Clinical Significance: This study will aid elucidating the role of magnesium sulphate gargles for the prevention of POST.

Keywords: Aspirin, Magnesium sulphate, Post-operative sore throat, Tracheal Intubation.

(Signature) Candidate	(Signature) Co-supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY."** exist in the Department of Anaesthesia at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
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Name of candidate	Jaspal Kaur
Department	Anaesthesia
Topic of Thesis	Comparative evaluation of aspirin and magnesium sulphate gargles for prevention of postoperative sore throat in patients undergoing lumbar laminectomy.
Likely date of appearing in PG examination	MAY/June , 2024
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Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
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Approved: Yes / ~~No~~

Dr. Sandeep Puri
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Approved: Yes / ~~No~~

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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	Jaspal Kaur
2	NAME OF THE INSTITUTE	DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA
3	COURSE OF STUDY AND SUBJECT	MD, Anaesthesiology
4	DATE OF ADMISSION OF COURSE	MARCH 4, 2022
5	TITLE OF THE TOPIC	Comparative evaluation of aspirin and magnesium sulphate gargles for prevention of postoperative sore throat in patients undergoing lumbar laminectomy.

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Post operative sore throat (POST) is a common complication after endotracheal intubation with reported incidence of 30-65%.[1-2] Most anesthesiologists regard POST as a minor and self-limiting problem. However, POST contributes to discomfort and morbidity for the patient.[3] In addition, there can be difficulty in phonation which can be quite demoralizing for the patient. Patients suffering from POST usually complain of irritation or itching in throat, discomfort, throat pain and coughing or hoarseness of voice. POST has the potential to prolong hospital stay and lead to dissatisfaction among the patients. Prevention of POST, therefore, is highly desirable.

In lumbar spine surgery, which is performed in the prone position, the incidence and severity of POST is expected to be higher and of greater severity due to the use of wire-reinforced tracheal tube which has a larger outer diameter[4] , requirement of concomitant use of a rigid stylet, and post intubation changes in patient position. Thus, efforts to reduce the occurrence of POST should be of high priority in this subset of patients.

There have been several studies looking at potential interventions with some benefits to prevent POST. Non pharmacological measures to prevent POST includes intubation using smaller size endotracheal tube, lubrication of endotracheal tube with water soluble jelly, careful airway instrumentation, intubation after full relaxation, minimum cuff pressure, gentle suctioning of oropharynx and extubation with full deflation of tracheal tube cuff.[5]

Intravenous (IV) dexamethasone due to its anti-inflammatory action has been widely used for prevention and management of POST.[6] However, hyperglycemia and predisposition to infection and poor wound healing due to use of steroids remain a concern.[7]To overcome this, various other pharmacological interventions have been employed which include aspirin gargles, inhalation of beclomethasone or gargling with azulene [8-9] or spraying benzydamine on endotracheal tube cuff,

use of topical or systemic lidocaine, ketamine gargles[10], zinc lozenges, amyl m cresol , ketoprofen, licorice and magnesium sulphate gargles.[11]

Aspirin is a commonly used, over the counter available Non Steroidal Anti Inflammatory Drug (NSAID) having analgesic, anti-pyretic and local anesthetic properties. Its action is mediated by inhibiting the prostaglandin system. Aspirin gargles have been observed to significantly reduce the incidences and severity of POST. [12]

Magnesium, an NMDA receptor antagonist acts as anti inflammatory and anti nociceptive by inhibiting NMDA Ca2+ influx. NMDA receptors also exist peripherally and inflammation stimulate peripheral NMDA receptors. Intravenous administration of magnesium has been demonstrated to have efficacy similar to that of dexamethasone for prevention of POST.[13] Borazan et al found magnesium lozenges to be effective for the prophylaxis of POST and attributed this effect to its wound healing properties.[14]Following this, Chattopadhay et al compared magnesium sulphate (MgSO4) gargles with aspirin gargles for the prevention of POST and found these to be superior. This is the only study in which MgSO4 gargles have been compared with aspirin gargles for the prevention of POST. The study, however was performed in patients undergoing short duration, ambulatory surgery. This cohort of patients have a less incidence of POST as compared to patients undergoing spine surgery in prone position.

Thus, the present study was planned to compare the efficacy of pre-induction gargles with magnesium sulphate and aspirin for prevention of POST in patients undergoing lumbar laminectomy in prone position.

6.2 REVIEW OF LITERATURE

Postoperative sore throat (POST) after endotracheal intubation is a common and annoying complication to the patient. Postoperative sore throat is a result of local tissue trauma due to laryngoscopy and endotracheal intubation, leading to the inflammation of pharyngeal mucosa. Tracheal intubation is associated with higher risk of postoperative sore throat than with a supraglottic airway or facemask. It causes trauma of the larynx posteriorly over the cricoid plate, along the vocal processes of arytenoids and along the anterior tracheal wall.

POST is attributed to multiple peri-operative conditions, including local irritation and inflammation of airway, [15] large size of the tracheal tube , increased duration of surgery , movement of tracheal tube and cuff during position change , airway damage after intubation using rigid stylet , and prone position[16] .Airway trauma during intubation or multiple attempts at intubation results in congestion and edema of pharyngolaryngeal mucosa, increasing the incidence and severity of POST.

Increased cuff pressure can also contributes to postoperative sore throat[17]. To reduce this complication, most measures have been directed at limiting the physical trauma from airway instrumentation and limiting the endotracheal tube cuff pressure. Several non pharmacological and pharmacological interventions have been evaluated for the prevention of POST, such as use of smaller endotracheal tube, topical or iv corticosteroids or local anesthetics , ketamine gargles , topical application of magnesium and others[16].

In 2006 Aggarwal et al conducted a prospective, randomized single blind study for evaluation of aspirin and benzydamine hydrochloride for attenuating postoperative sore throat prevention on 60 patients, concluded that Aspirin and benzydamine hydrochloride gargles significantly reduced the incidence and severity of post operative sore throat (POST)[12].

Salama and Badawy in a study reported that preoperative nebulisation with dexamethasone 8mg reduces the incidence and severity of

postoperative sore throat in patients receiving general anaesthesia with endotracheal intubation[19].

Gupta D and Ghanshyam Y studied the efficacy of licorice gargles for attenuating post operative sore throat on fourty adults of 18-60 yrs of age, ASA I and II of either sex, undergoing elective lumbar laminectomy concluded that POST and postextubation cough was reduced in licorice group compared with control group.There was no side effects between groups.[20]

In an another study ,Ogata et al. observed that preoperative gargling with azulene reduced the incidence of POST from 65% to 25% in patients due to its anti inflammatory effects[9].

Canbay et al conducted a study on ketamine gargles for attenuating postoperative sore throat after endotracheal intubation on Fourty-six, ASA 1&2,patients and concluded that POST was significantly less in patients administered with ketamine gargles at 0,2 and 24hrs.[10]

Borazan et al in 2012 conducted a study on magnesium lozenges and placebo group and concluded that the severity of POST was significantly lower in magnesium group at 0 and 2 hr. The incidence of POST however was similar in both groups at 24 hrs.[14]

Farhang B and Grondin L in 2017 conducted a study on the effect of Zinc lozenges on postoperative sore throat prevention and concluded that the severity of POST was significantly lower in the zinc group for mild and moderate POST.

Subedi et al in 2019 conducted a prospective, randomized, double blind study on the effect of intravenous lidocaine(L), dexamethasone(D) and their combination(DL) on post operative sore throat and concluded that the incidence of a sore throat was 36% , 43% , 25% and 56% in Group D , L , DL and NS. Dexamethasone with or without lidocaine reduced the incidence of the post operative sore throat (POST). No differences was observed in the severity of sore throat, cough and hoarseness among the groups.

Kumar et al conducted a study in 2017 on postoperative sore throat in head and neck surgeries under endotracheal intubation and laryngeal mask anesthesia. During different cuff pressure and size of tube or

mask, pain score was measured. They concluded that the postoperative sore throat can be effectively reduced by LMA but they were not able to find any correlation of pain score with different cuff pressure and size of tube or mask

Dipanjan et al conducted a study on the efficacy of intravenous dexamethasone to reduce the incidence of postoperative sore throat and concluded that in the first 24hrs there is overall decrease in the incidence and the severity was lower after prophylactic intravenous dexamethasone. Postoperative sore throat is caused by aseptic inflammatory process to the tracheal mucosa during laryngoscopy, increased cuff pressure and during extubation. Dexamethasone prevents POST by inhibiting metabolism of arachidonic acid, thus reducing cytokine release.

In the year 2015, Teymourian et al conducted a study to compare the efficacy of magnesium sulphate and ketamine gargles on incidence and severity of POST and came to the conclusion that the number of patients with sore throat were significantly lower in magnesium group compared to ketamine at 2 and 24 hrs and Visual Analogue Scale (VAS) score was significantly lower in magnesium group at 2 and 24 hours after the surgery.[21]

Aspirin has been used in many studies for the prevention of POST but there has been only one study comparing aspirin with magnesium for the prophylaxis of POST. Thus, there is dearth of literature on the relative efficacy of aspirin and magnesium for prophylaxis of POST. Therefore, the present study has been designed to evaluate the efficacy of Aspirin and Magnesium sulphate gargles for prevention of postoperative sore throat prevention in patients undergoing lumbar laminectomy in prone position.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the efficacy and safety of preoperative gargles with aspirin and magnesium sulphate for prevention of postoperative sore throat.

7. MATERIAL AND METHODS

7.1 SOURCE OF DATA

The study will be conducted in a prospective, randomized, double blinded manner in the department of Anaesthesiology, DMCH, Ludhiana after obtaining clearance from hospital ethics committee. Sixty patients of either sex between age group 18 to 65 years belonging to ASA grade I,II and III scheduled for elective lumbar laminectomy under general anaesthesia will be randomly allocated to two groups of 30 patients each

Group Allocation

Patients will be randomly allocated into two groups, Group A and B, of 30 patients each using computer generated random number list which will be kept in a sealed opaque envelope and opened at the completion of study. The study solution will be prepared and administered by an anesthesia resident who will not take further part in the management of patient. Patients in both groups will gargle the study solution for 30 seconds, 15 minutes before induction of anesthesia.

Group A - Patients will receive gargle solution prepared by dissolving a tablet of Aspirin 325 mg in 20 ml of 5 % dextrose.

Group B - Patients will receive gargle solution prepared by dissolving 2 ml of Magnesium sulphate (50 % w/v) in 20 ml of 5 % dextrose.

The anesthesia resident monitoring the patient in post anesthesia care unit (PACU) will not be aware of the group allocation.

7.2 METHOD OF COLLECTION OF DATA

INCLUSION CRITERIA :

- Adult patients of age 18-65 years of either sex posted for elective lumbar laminectomy under general anaesthesia with endotracheal intubation.
- American Society Of Anesthesiologists (ASA) Status I, II and III.

EXCLUSION CRITERIA:

Patient would be excluded from the study if they had any of the following:

- Patient refusal.
- Any known hypersenstivity or contraindication to aspirin, magnesium sulphate.
- Recent H/O Sore throat.
- Pregnant & lactating mothers.
- Anticipated difficult intubation, MPS Grade III and IV.
- Patients receiving chronic treatment with calcium channel blocking drugs or magnesium.
- Patients on steroids.
- History of reactive airway disease like bronchial asthma or COPD.

ANAESTHESIA TECHNIQUE

A detailed pre-anaesthetic checkup will be conducted preoperatively one day prior to surgery comprising of detailed history, general physical and systemic examination. Routine investigations like complete hemogram, prothrombin time/INR, urine routine, renal function tests, random blood sugar, chest X-ray and ECG will be done. Patients will be counselled and explained about the scoring system to be used for evaluation of POST.

All patients will be kept nil per oral before surgery. This fasting period would be eight hours for solids and 4 hours for clear liquids. Pre-medication in the form of tab alprazolam 0.5 mg on the night before surgery will be administered to all patients. Vitals will be monitored again in the pre-operative holding area. Fifteen minutes before induction of anaesthesia, patients will be requested to perform gargles for 30 seconds using the study drug solution as per random group allocation.

Group A - Patients will be administered solution prepared by dissolving a tablet of Aspirin 325 mg in 20 ml of 5 % dextrose.

Group B - Patients will be administered solution prepared by dissolving 2 ml of Magnesium sulphate (50 % w/v) in 20 ml of 5 % dextrose.

Throat would be examined by the anesthesia resident pre and post gargles and after extubation.[22]

After arrival of patient to the operating room, standard monitoring including continuous electrocardiography (ECG), non-invasive blood pressure (NIBP) and oxygen saturation by pulse oximeter(SpO_2) will be started and baseline parameters will be recorded. Intravenous line will be secured using an 18 gauge cannula and intravenous fluid will be infused.

After standard anaesthesia induction, using intravenous propofol, patients will be paralyzed using Inj atracurium 0.5 mg/Kg and endotracheal intubation will be performed using a high volume, low pressure cuffed flexometallic endotracheal tube(Romsons) of size 7.5 internal diameter (ID) for females and 8.0 for males. The ETT with stylet but without lubrication would be inserted using direct laryngoscopy technique by a designated anesthesia consultant . Any pateint where more than one attempt was required for intubation would be excluded from the study. Endotracheal tube cuff would be inflated and cuff pressure measured using ETT cuff pressure manometer. Intra-operatively, anaesthesia will be maintained using oxygen, nitrous oxide and desflurane. Intra-operative analgesia will be provided by bolus injections of fentanyl. Volatile agent concentration, muscle relaxant and analgesic administration will be titrated as per the discretion of anaesthesiologist. ETT cuff pressure would be measured every 30 minutes and maintained between 22-25 cmH2O by deflating the cuff a little if so required.

Patients will be continuously monitored for the duration of surgery and vitals will be recorded every 5 minutes.

At the end of surgery, patients would be administered Inj ondansetron 0.1mg/kg and paracetamol 15mg/kg intravenous infusion. After completion of surgery, neuromuscular blockade would be reversed using Inj neostigmine 0.5mg/kg and glycopyrolate0.01mg/kg and ETT would be removed after gentle suctioning of oropharynx and deflating the ETT cuff.

On arrival to Post anaesthesia care unit (PACU), patients will be evaluated for sore throat at 1, 2, 4 ,12 and 24 hrs which will be graded using Numerical Rating Scale(NRS), marked from 0 to 10, where 0 means no sore throat and 10 means worst imaginable pain in throat.

NUMERICAL RATING SCALE

No Pain

Worst Pain

Patients would also be assessed on 4-graded scale, wherein

GRADE 0- No sore throat

GRADE 1-Mild sore throat (complains only on asking)

GRADE 2-Moderate sore throat (complains on his/her own)

GRADE 3-Severe sore throat (hoarseness, throat pain)

Patients will also be asked whether they experience any side effects related to the gargle solution.

OUTCOME:

PRIMARY OUTCOME:

1. Incidence of sore throat.
2. Severity of sore throat as assesed by NRS and subjective grading score.

SECONDARY OUTCOME:

1. Incidence of post extubation cough

STATISTICAL ANALYSIS:

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data is normally distributed, a Kolmogorov-Smirnov test will be used. Comparison of quantitative variables between the study groups will be

done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test will be performed and fisher exact test will be used when the expected frequency is less than 5. A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows

SAMPLE SIZE CALCULATION

By using previous study[11], the Postoperative sore throat is 18% in magnesium group and 39% in Aspirin group.

Based on this assumption

The formula used in the situation is as under:

$$n = \frac{[Z_{1-\alpha/2}\sqrt{2\,P\,(1-P)} + Z_{1-\beta}.\sqrt{\{P1(1-P1) + P2\,(1-P2)\}}]^2}{(P1-P2)^2}$$

Where P=(P1+P2)/2

- Approximate value of efficacy/cure rate for standard treatment =P1
- Approximate value of efficacy/cure rate for other treatment = P2
- Effect size = (P2-P1)
- Level of significance (usually 5%)
- Zα = Value of standard normal variate corresponding to α level of significance (1.96)
- Zβ = The standard normal deviate for desired power(0.842)

With the above assumptions the sample size for 95% confidence level & 80% power works out 66 in each group.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Yes, Attached herewith

8. LIST OF REFERENCES

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throat, hoarseness, and cough after tracheal intubation. Anesth Analg. 1998;87:714–6.

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PROFORMA

S.No Randomization no.

Mrd No Age/Gender

Height Weight

BMI ASA Grade

Date of Surgery Diagnosis

Surgery Performed Time of Gargling

Time of Start of Anaesthesia Time of Intubation

Time of Shifting to P.A.C.U. Time of Extubation

INTRAOPERATIVE ENDOTRACHEAL CUFF PRESSURE MONITORING

INTRAOPERATIVE MINUTE	ETT CUFF PRESSURE
30min	
60min	
90min	
120min	
150min	
180min	

Signature of Candidate **Signature of Supervisor**

AFTER SHIFTING TO P.A.C.U.

	1hr	*2hr*	*4hr*	*12hr*	*24hr*
Grade of POST					
NRS Score					

	0hr	*1hr*	*2hr*	*4hr*	*12hr*	*24hr*
Grade of cough						

THROAT EXAMINATION

Clinical findings	*Pre gargles*	*Post gargles*	*Post extubation*
Absence or presence of erythema/swelling in pharyngeal or tonsillar area			

PICTURE OF THROAT AFTER GARGLES

GRADING OF SORE THROAT

GRADE 0- No sore throat

GRADE 1-Mild sore throat (complains only on asking)

GRADE 2-Moderate sore throat (complains on his/her own)

GRADE 3-Severe sore throat (hoarseness, throat pain)

Signature of Candidate **Signature of Supervisor**

GRADING OF COUGH

0 No cough
1 Mild (less than common cold)
2 Moderate(similar to common cold)
3 Severe(more than a common cold

ADVERSE EFFECTS IF ANY:

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I…….D/o, W/o, S/o……..…… am willing to participate in the study **"COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

……. ……
Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य "**COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY**" में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____	_____
गवाह के हस्ताक्षर	रोगी के हस्ताक्षर/अंगूठे का निशान
नाम:	नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

“COMPARATIVE EVALUATION OF ASPIRIN AND MAGNESIUM SULPHATE GARGLES FOR PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY” ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ